Biotech Daily

Wednesday January 30, 2013

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ANTISENSE UP 23%, SUNSHINE HEART DOWN 10%**

*** MESOBLAST READY FOR PHASE II RHEUMATOID ARTHRITIS TRIALS**

*** ACRUX JUMPS 8% ON 2012 AXIRON SALES UP 208% TO $71m**

*** ANTISENSE: FDA APPROVES ISIS, GENZYME KYNAMRO**

*** REGENEUS, KOLLING: 'FAT STEM CELLS HELP DOG CANCER VACCINE'**

*** SUNSHINE HEART HOPES TO DEPART ASX BY JULY**

*** WARREN WATSON REPLACES SUNSHINE HEART'S DR WILLIAM PETERS**

*** CALZADA EARNS $789k FEDERAL R&D TAX REFUND**

*** EMA DISCUSSES DELAYED TISSUE THERAPIES VITROGRO**

MARKET REPORT

The Australian stock market climbed 0.16 percent on Wednesday January 30, 2013, with the S&P ASX 200 up 7.7 points to 4,896.7 points. Fourteen of the Biotech Daily Top 40 stocks were up, 12 fell, eight traded unchanged and six were untraded.

Antisense was the best, up 0.3 cents or 23.1 percent to 1.6 cents with 56.2 million shares traded, followed by Impedimed up 18.75 percent to 9.5 cents with 2.3 million shares traded on improved quarterly sales and reduced costs.

Acrux climbed 8.1 percent; Benitec was up 6.7 percent; Allied Health, Cellmid, Mesoblast, Optiscan and Prima were up more than four percent; Alchemia was up three percent; Anteo, Heartware, Reva and Universal Biosensors were up more than one percent; with CSL up 0.7 percent.

Sunshine Heart led the falls, down 0.3 cents or 10 percent to 2.7 cents with 1.5 million shares traded.

Circadian lost 6.1 percent; QRX was down 5.9 percent; Avita fell four percent; Bionomics, Phosphagenics, Phylogica and Starpharma were down more than three percent; Genetic Technologies, Medical Developments and Sirtex shed more that two percent; GI Dynamics was down 1.3 percent; with Cochlear and Resmed down less than one percent.

MESOBLAST

Mesoblast says the US Food and Drug Administration has cleared a 48-patient, phase II trial of its mesenchymal precursor cells for active rheumatoid arthritis.

Mesoblast said that the randomized, double-blind, placebo-controlled trial would evaluate a single intravenous infusion of the allogeneic, or off-the-shelf, mesenchymal precursor cells and was expected to begin in the US and Australia by July 2013.

The company said that the trial would compare the effects of a single intravenous infusion of allogeneic mesenchymal precursor cells dosed at 1.0 million cells/kg or 2.0 million cells/kg compared with placebo in patients with an incomplete or inadequate response to a biologic inhibitor of the tumor necrosis factor-alpha (TNF-alpha) pathway for active rheumatoid arthritis.

Mesoblast said that safety and effectiveness of the therapy would be assessed at multiple time points with the primary endpoints defined as three months.

The company said that a second phase II active rheumatoid arthritis trial was planned to begin in Europe by July 2013.

The company said that rheumatoid arthritis was an autoimmune disease caused by aberrant activation of multiple immune pathways involving both monocytes and T-cells, ultimately resulting in joint destruction.

Mesoblast said that existing biologic treatments targeted single immune pathways, resulting in incomplete responses, the need for chronic administration and potentially unacceptable infectious adverse events.

Mesoblast said that its stem cells had been shown in preclinical studies to have a broad immuno-modulatory mechanism of action, simultaneously inhibiting T-cells and monocytes involved in inflammation and autoimmunity.

The company said that the broader effects of its cells on multiple immune pathways suggested that they could be useful agents for reducing the inflammation and permanent joint damage associated with progression of rheumatoid arthritis.

Mesoblast said that a randomized, placebo-controlled study in 30 sheep with collagen-induced arthritis, showed the cells reduced TNF-alpha, interleukin-6 (IL-6), and IL-17 in the diseased joint (BD: Jul 24, 2012).

The company said that in comparison with saline treated controls, synovial tissue from arthritic sheep 30 days after receiving a single intravenous injection of 2.0 million cells/kg showed an 88 percent reduction in IL-6 levels ($p = 0.029$), 83 percent reduction in TNF-alpha levels ($p = 0.049$), 53 percent reduction in IL-17 levels ($p = 0.005$) and a 43 percent reduction in infiltrating monocytes/macrophages ($p = 0.018$).

Mesoblast said that mesenchymal precursor cell-treated animals had a 31 percent reduction in histopathology severity scores compared with controls ($p < 0.025$).

The company said that the findings showed that mesenchymal precursor cells (MPCs) could concomitantly inhibit both Th17 T-cells and pro-inflammatory monocytes and improve synovial tissue pathology, providing a rationale for their potential use as both a first-line biologic treatment in those not responding to conventional anti-rheumatic agents and in patients with incomplete responses to biologic inhibitors of the TNF-alpha pathway alone.

Mesoblast chief executive Prof Silviu Itescu said the company believed that “the broad immuno-modulatory effects of our MPCs could provide a tangible benefit to patients with debilitating autoimmune diseases, including [rheumatoid arthritis]”.

“This is the first in a series of programs designed to establish the credentials of our intravenous product formulation for a broad-based spectrum of inflammatory and immunologic conditions,” Prof Itescu said.

Mesoblast was up 23 cents or 4.1 percent to $5.80 with 237,726 shares traded.

ACRUX

Eli Lilly has published its 2012 sales figures showing Acrux's Axiron increasing 207.9 percent to $US73.9 million ($A70.7 million) for the year to December 31, 2012.
Eli Lilly said that from the start of Axiron sales in April 2011 to December 31, 2011, the year's sales total was $US24.0 million.
The US-based company said that in 2012, Axiron sales were $US16.3 million in the three months to March 31; $US17.7 in the three months to June 30; $US16.0 in the three months to September 30 and $US23.9 million in the three months to December 31.
Acrux chief financial officer Jon Pilcher told Biotech Daily that the increased sales figures on the back of a television advertising campaign and improved product awareness gave Acrux confidence that the $25 million royalty figure for reaching $100 million in sales in a calendar year would be achieved in 2013.
Mr Pilcher said that the royalty rate was on an increasing scale but Acrux was entitled to 11 percent of current sales.
Mr Pilcher said that Axiron had about 13 or 14 percent of the total US transdermal testosterone market worth about $US2 billion in gross sales.
Acrux closed up 26 cents or 8.1 percent to $3.46 with 1.6 million shares traded.

ANTISENSE THERAPEUTICS

Antisense says that the US Food and Drug Administration has approved Kynamro, developed by technology partner Isis Pharmaceuticals with Sanofi's Genzyme.
Antisense said that Kynamro, for patients with homozygous familial hypercholesterolemia, was a second generation antisense drug with the same platform chemistry as the compounds in its pipeline, with similar characteristics such as the way they were distributed and cleared by the body.
The company said that Isis had announced that Kynamro was the first systemic or injectable antisense drug to reach the market and was the culmination of two decades of work to create a new, more efficient drug technology platform.
Isis and Genzyme said that Kynamro, given as a 200mg weekly subcutaneous injection, had been approved as an adjunct to lipid-lowering medications and diet to reduce low density lipoprotein-cholesterol, apolipoprotein B, total cholesterol and non-high density lipoprotein-cholesterol in patients with homozygous familial hypercholesterolemia.
Last year, Isis and Antisense had significant price falls on concerns that the US Food and Drug Administration's Endocrinologic and Metabolic Drugs Advisory Committee might reject an application for Sanofi's Genzyme Kynamro (mipomersen sodium) to lower low-density lipoprotein cholesterol, due to liver toxicity issues (BD: Oct 17, 2012).
But the Committee voted nine-to-six that Genzyme had provided sufficient efficacy and safety data to support the marketing of Kynamro to lower low-density lipoprotein cholesterol in patients with homozygous familial hypercholesterolemia (BD: Oct 19, 2012).
In December Antisense reported that the European Committee for Medicinal Products for Human Use had adopted a negative opinion for its marketing authorization application for Kynamro or mipomersen for the treatment of patients with homozygous familial hypercholesterolaemia and Genzyme said it would request a re-examination of the Committee opinion (BD: Dec 17, 2012).
Antisense was up 0.3 cents or 23.1 percent to 1.6 cents with 56.2 million shares traded.

REGENEUS

Regeneus says that with researchers at Sydney's Kolling Institute of Medical Research, its fat-based stem cells improve the effect of a cell-based cancer treatment vaccine in dogs.
Regeneus said that the Kolling Institute's Dr Chris Weir and Prof Ross Davey, based at the Royal North Shore Hospital discovered a novel way to produce a cancer treatment by making a vaccine using a patient's own tumor cells.
The company said that the vaccine involved the removal of the tumor or a biopsy from the patient to produce a personalized vaccine, which stimulated the immune system to see the cancer cells as foreign and helped prevent further growth of the tumor as well as development of new tumors.
Regeneus said that as part of the collaboration, Dr Weir wanted to test whether adipose-derived stem cells would enhance the performance of the vaccine and used a preparation of adipose stem cells from Regeneus in an animal model of brain cancer and found that the injection of stem cells with the vaccine resulted in an increase in the life span of the animals.
Dr Weir said that initial results with vaccine-treated stem cells were "very promising".
"These preliminary results are significantly better than the vaccine alone," Dr Weir said.
"We are not aware of any other research showing this effect," Dr Weir.
"For the past two years we have been collaborating with leading veterinary oncologists and preparing vaccines to treat dogs with cancer using the vaccine alone but based on this initial study we would like to trial it in combination with the stem cells in a new study," said Dr Weir.
Regeneus chief executive officer Prof Graham Vesey said his company was "excited that our adipose stem cell technology has potential application with cancer vaccine therapies".
"Up to this point our technology has been limited to the treatment of osteoarthritis and other musculoskeletal conditions in humans and animals," Dr Vesey said.
"We are also interested to explore other cancer treatment opportunities for our adipose stem cell technology," Dr Vesey said.
Regeneus said that patent applications had been lodged in relation to the vaccine technology as well as the use of adipose stem cells with the vaccine.
The company said it would fund the next phase of the research in return for exclusive commercialization rights to the cancer vaccine for veterinary and human applications.
Regeneus is a public unlisted company.

SUNSHINE HEART

Sunshine Heart says it intends to de-list from the ASX by July 2013.
Sunshine Heart said it was listed on both the ASX and the Nasdaq and believed it was "in the best interest of the company and all of its shareholders" that it depart from the ASX.
Sunshine Heart listed on the Nasdaq in last year and raised $17 million of a hoped for $27 million for a pivotal trial of its C-Pulse aorta pump system (BD: Feb 15, Aug 16, 2012).
The company said that reasons for the departure included low liquidity in trading in Chess Depositary Interests (CDIs) on ASX compared to common shares on Nasdaq.
Sunshine Heart said that an average of 4.2 percent of all trades in the company's securities were executed through ASX in the three months to December 31, 2012.
The company said that the CDIs on the Australian register were 18.9 percent of the total issued capital and 17.4 percent excluding the directors' holdings and shareholders with holdings of greater than 5 percent at January 18, 2013.
Sunshine Heart said its US common shares would continue to be listed on the Nasdaq.
Sunshine Heart fell 0.3 cents or 10 percent to 2.7 cents with 1.5 million shares traded.

SUNSHINE HEART

Separately, Sunshine Heart said that Warren Watson would replace C-Pulse inventor and company co-founder Dr William Peters as a director, effective immediately.
Sunshine Heart said that Dr Peters would continue as chief technical officer.
The company said that Mr Watson had more than 35 years of experience in medical devices, including 33 years at Medtronic, where he served in roles from technical management, clinical and regulatory processes, business development and strategic marketing to general management, including spent eight years as vice-president of cardiac rhythm management research and development.
Sunshine Heart said that Mr Watson had served as a director of several US cardiology companies, was a director of California-based cardiology company, Cameron Health, which was bought by Boston Scientific in 2012 and currently was a director of two Minneapolis-based medical device companies Cardialen Inc and Cardia Access.

CALZADA

Calzada says it has received $789,254 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Calzada said the funds related to research and development expenditure for the year to June 30, 2012.
Calzada fell 0.4 cents or 8.2 percent to 4.5 cents.

TISSUE THERAPIES

Tissue Therapies says that the European Medicines Agency discussed its Vitrogro wound treatment application at its January meeting but did not complete deliberations.
Tissue Therapies said that the British Standards Institute, the notified body responsible for approval, believed a conclusion would be reached at the February meeting of the EMA Committee for Medicinal Products for Human Use, with the company notified on or about February 25, 2013.
Tissue Therapies chief executive officer Dr Steven Mercer told Biotech Daily that should the formal review start date be approved by the Committee in February, the company would expect Conformité Européenne (CE) mark approval in August 2013.
Tissue Therapies was unchanged at 29 cents.