Biotech Daily

Wednesday June 25, 2014

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: BIONOMICS UP 13%, COMPUMEDICS DOWN 10%**

*** AVEXA REASSERTS ITS APRICITABINE (ATC) PROGRAM FOR HIV**

*** US TRIALS NETWORK CONTINUES MESOBLAST CARDIAC RESEARCH**

*** ITL PROFIT WARNING**

*** MAYNE COMPLETES HEDGEPATH SUBA-ITRACONZAOLE LICENCE**

*** VICTORIA: BILL CLINTON, BOB GELDOF FOR AIDS 2014 IN MELBOURNE**

MARKET REPORT

The Australian stock market fell 0.57 percent on Wednesday June 25, 2014 with the S&P ASX 200 down 30.8 points to 5,402.0 points.

Ten of the Biotech Daily Top 40 stocks were up, 16 fell, 13 traded unchanged and one was untraded.

Bionomics was the best for the second day in a row, up seven cents or 13.2 percent to 60 cents with 3.7 million shares traded, followed by Ellex up 11.8 percent to 38 cents with 17,989 shares traded.

Neuren climbed 6.3 percent; Clinuvel and Pharmaxis were up more than four percent; Alchemia, Medical Developments, Phosphagenics and Psivida rose more than two percent; Benitec was up 1.8 percent; with Cochlear up 0.8 percent.

Compumedics led the falls, down 1.5 cents or 10.3 percent to 13 cents with 361,000 shares traded.

Antisense lost 6.9 percent; Impedimed and Optiscan fell more than five percent; both Avita and Universal Biosensors fell 4.35 percent; Acrux, Admedus and Tissue Therapies were down more than three percent; Analytica and Genetic Technologies shed more than two percent; GI Dynamics and Mesoblast were down more than one percent; with CSL, Nanosonics, Resmed, Sirtex and Starpharma down by less than one percent.

AVEXA

Avexa chairman Iain Kirkwood is leading a roadshow to demonstrate that the company is ready for a pivotal phase III trial of apricitabine (ATC) for HIV.

Mr Kirkwood said that the series of investor presentations, entitled 'Changing market perceptions' confirmed that the company expected revenue from its Alabama coal mine by the end of 2014 to fund a 300-patient, three-arm phase III trial approved by both the US Food and Drug Administration and the European Medicines Agency.

"We're back," Mr Kirkwood said, referring to a board spill and an ongoing fight for control with Calzada in 2010 (BD: May 24, 26, Aug 10, Oct 19, 2010).

"We have a clinical trial ready to go, revenue coming from the sale of coal or the mine and the named patient scheme and no need to raise funds," Mr Kirkwood said.

Mr Kirkwood said that Avexa had invested $9 million in loans and equity for the Alabama coal mine and held 30 percent with Avexa major shareholder, Singapore's Jonathan Lim, holding a further 30 percent and US interests holding the balance.

The internal problems followed Avexa dropping its lead phase III program of apricitabine or ATC for HIV, the resignation of the chief executive officer Dr Julian Chick and a request for a board spill (BD: May 10, 2010).

Avexa previously demonstrated that apricitabine had efficacy and of the 36 patients who successfully completed the phase II study, "94 percent [34 patients] maintained undetectable viral loads up to week 144", and the 24-week data from its phase III HIV trial showed a non-significant positive clinical benefit for apricitabine compared to the standard of care, 3TC (BD: Feb 4, 5 and 15, 2010).

Today, chief scientific officer and acting chief executive officer Dr Jonathan Coates said told Biotech Daily that there remained a great need for HIV drugs as the numbers of people with HIV increased despite education programs and the virus became increasingly drug resistant.

Dr Coates said that 80 percent of Europeans with HIV were not fully suppressed and were heading towards AIDS.

He said that the number of people with drug-resistant HIV had increased by 35 percent since 2003 with the most common resistance to existing nucleoside reverse transcriptase inhibitors and that meant there was a role for ATC which was a new dug in that class and had shown that it "worked in naïve patients so it would be effective as a first line therapy".

Avexa's head of drug development Dr Susan Cox said the planned $30 million 300-patient phase III trial would compare the control group on 3TC with two other anti-viral drugs to 800mg of ATC and 1200mg of ATC also in combination with two other anti-viral drugs.

Dr Cox said that the 1200mg group was primarily to ensure safety of the drug and that the trial's primary endpoint was efficacy as measured by viral load at 14 days.

Mr Kirkwood said that the company required revenue before it would begin the trial and "it is effectively waiting for the coal mine" which he said expected revenue from coal production by the end of 2014.

Dr Coates said that Avexa expected some small revenue for a named-patient or compassionate use scheme being administered by the Singapore based Link Healthcare.

Dr Coates said the company had sufficient stocks of Apricitabine for both the phase III trial and a named-patient scheme.

Dr Coates said the company also had a separate pre-clinical integrase inhibitor program for HIV which had shown activity against both wild type and resistant HIV and had with a large number of potential compounds, as well as the anti-bacterial program which had been licenced to the Switzerland-based Valevia.

Avexa fell 0.2 cents or 14.3 percent to 1.2 cents.

MESOBLAST

Mesoblast says that the US Cardiothoracic Surgical Trials Network is planning further trials of its stem cells for heart failure patients with heart pumps.

Mesoblast said that the results of the phase II trial of its mesenchymal stem cells injected into the hearts of patients with left ventricular assist devices had been published in the American Heart Association journal Circulation.

Last year, Mesoblast published the research led by New York's Mount Sinai Hospital school of medicine evaluating mesenchymal precursor cells in patients with end-stage or class IV heart failure who received a left ventricular assist device (BD: Nov 19, 2014).

The trial was sponsored and funded by the US National Institutes of Health and coordinated by the NIH-funded Cardiothoracic Surgical Trials Network.

The Circulation article, entitled 'Mesenchymal Precursor Cells as Adjunctive Therapy in Recipients of Contemporary LVADs' concluded that mesenchymal precursor cells "appeared to be safe and there was a potential signal of efficacy".

"Future studies will evaluate the potential for higher or additional doses to enhance the ability to wean [left ventricular assist device] recipients off support," the Cardiothoracic Surgical Trials Network said.

An abstract is available at: http://bit.ly/1loAP6d.

Mesoblast chief executive Prof Silviu Itescu told Biotech Daily that the Cardiothoracic Surgical Trials Network was "indeed planning a next study with Mesoblast's cells ... using a higher dose or additional doses".

"When we have specific news on the next study, we will inform the market," Prof Itescu said.

Last year, Mesoblast reported t that a single injection of 25 million allogeneic, or off-the-shelf, mesenchymal precursor cells (MPCs) resulted in an improvement in cardiac function at 90 days, as measured by the ability of the native heart to support the circulation with the left ventricular assist device temporarily turned down.

Mesoblast said that the trial randomized 30 end-stage heart failure patients two-to-one to receive either a single 25 million dose injection of MPCs or control media into the native heart at the time of device implantation.

The company said at that time that device weaning, or transient reduction in pump speed for at least 20 minutes, was attempted in all patients at predetermined intervals to assess native myocardial function and patients were followed for one year or until heart transplantation, whichever came first.

Mesoblast said that at 90 days, 50 percent of MPC-treated patients were able to tolerate being temporarily weaned from their devices compared with 20 percent of controls and none of the 20 MPC-treated patients died compared with three of 10 control patients.

Mesoblast said that improved cardiac function was sustained over the 12-month follow-up period with 85 percent of MPC-treated patients weaned successfully on multiple occasions compared with 40 percent of controls.

Mesoblast fell eight cents or 1.8 percent to $4.36 with 598,868 shares traded.

ITL

ITL says it expects net profit after tax for the year to June 30, 2014 to be down 25 percent to $1.9 million.

ITL said it specialized in medical devices and procedure packs and manufactured in Australia and Malaysia, with sales offices in Australia, North America and Asia.

ITL was unchanged at 21 cents.

MAYNE PHARMA GROUP

Mayne Pharma says it has out-licenced its Suba-itraconzaole intellectual property to the Tampa, Florida-based Hedgepath Pharmaceuticals for a 41.5 percent equity stake.
Mayne said that Hedgepath had secured further funding for the clinical development, registration and commercialization of the oral formulation of itraconazole, for the treatment of a variety of cancers in the US.
Last year, Mayne first announced the licence for between 30 and 45 percent stake in Hedgepath (BD: Sep 11, 2013).
In 2010, Mayne Pharma (then Halcygen) completed a 175-patient, phase II US study showing Suba-itraconazole superiority over itraconazole for fungal infections and in 2013, Mayne said it had UK approval and had begun two US pivotal studies of Subacap (Suba-itraconazole) for fungal infections (BD: Apr 13, 2010; Dec 15, 2011; Jun 17, 2013).
Today, Mayne said it had appointed one director to the Hedgepath board and two members to the joint development committee and it would supply Suba-itraconazole for trials and exclusive supply following US Food and Drug Administration approval.
Mayne said the agreement was separate to its commercializing Suba-itraconazole for fungal infections.
Mayne said it would recognize $4 million to $4.5 million non-cash revenue for accounting purposes, subject to the completion of a final valuation.
Mayne chief executive officer Scott Richards said that Hedgepath was expected to file an investigational new drug application “shortly and then commence a phase II study of basal cell carcinoma in patients with basal cell carcinoma nevus syndrome in the coming year”.
Mayne fell one cent or 1.1 percent to 87.5 cents.

AIDS 2014, VICTORIA GOVERNMENT

Victoria Minister for Health David Davis says that former US President Bill Clinton and musician activist Bob Geldof will address the AIDS 2014 conference in Melbourne in July.
“Both these men are global change agents and world leaders and have mobilized enormous international efforts to reduce poverty and respond to the HIV epidemic,” Mr Davis said.
“Their presence further enhances the very strong program that has been put in place for AIDS 2014,” Mr Davis said.
Mr Davis said President Clinton had a “very strong track record in advocating for HIV/AIDS treatment in disadvantaged communities around the world”.
“When the Clinton Health Access Initiative was founded in 2002, only 200,000 people were receiving treatment for HIV/AIDS in low and middle income countries, with medicines that cost over $10,000 per person per year,” Mr Davis said.
“Now, more than a decade later, more than eight million people are receiving treatment and [the Initiative] has helped reduce the cost of medicines to around $100 to $200 per person per year in many countries.
Mr Davis said that Mr Geldof “has the ability to motivate millions of people as we have seen over decades of activism”.
“His music and such events as Live Aid and Band Aid have raised global awareness of famine and poverty,” Mr Davis said.
The Melbourne conference will be held from July 20 to 25, 2014.
For more information got to: http://www.aids2014.org.