Biotech Daily

Tuesday March 19, 2013

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: TISSUE THERA UP 10%, IMPEDIMED DOWN 11%**

*** FDA REFUSES PHARMAXIS BRONCHITOL APPLICATION**

*** HEARTWARE RAISES $143m**

*** BIOTRON PHASE I/II TRIAL: 'BIT225 KILLS HIV IN RESERVOIR CELLS'**

*** GENETIC TECHNOLOGIES BEGINS EURO PATENT ASSERTION PROGRAM**

*** ANTISENSE TO PAY UP TO $300k FOR CHINA TOXICOLOGY STUDY**

*** RESONANCE WINS EUROPEAN TRIAL CONTRACT**

*** ISONEA TAKES ASTHMA MONITOR TO CLOUD COMPUTING**

MARKET REPORT

The Australian stock market fell 0.56 percent on Tuesday March 19, 2013 with the S&P ASX 200 down 28 points to 4,987.4 points.

Ten of the Biotech Daily Top 40 stocks were up, 15 fell, 12 traded unchanged and three were untraded.

Tissue Therapies was the best, recovering from yesterday's 55 percent fall, up 1.5 cents or 9.7 percent to 17 cents, with 1.2 million shares traded.

Phosphagenics and Prana climbed more than eight percent; Circadian was up 3.6 percent; Atcor and Mesoblast rose more than two percent; with Anteo, Clinuvel, Genetic Technologies, Resmed and Reva up one percent or more.

Impedimed led the falls, down one cent or 11.1 percent to eight cents with 68,996 shares traded, followed by Osprey down 9.6 percent to 47 cents with 9,850 shares traded.

Pharmaxis lost 7.1 percent; Viralytics was down 6.45 percent; Avita fell four percent; Alchemia, Phylogica and QRX were down more than three percent; Cellmid, Medical Developments, Psivida, Sirtex and Starpharma shed more than two percent; Bionomics and CSL were down more than one percent; with Acrux and Cochlear down by less than one percent.

PHARMAXIS

The US Food and Drug Administration has rejected the Pharmaxis application for Bronchitol for cystic fibrosis, recommending an additional clinical trial.

Pharmaxis reported the FDA complete response letter saying: “The submitted data do not provide a favorable benefit-risk balance to support the use of inhaled mannitol in patients with cystic fibrosis six years of age and older”.

“The determination of efficacy based on the two clinical trials are not adequate because of the treatment-related frequent early dropouts in trial 301 for which the primary statistical analyses did not account and the lack of statistical significance in trial 302 for the primary endpoint,“ the FDA complete response letter said.

Pharmaxis said that in relation to safety, the FDA stated its concern with the occurrence of haemoptysis, or coughing blood from the respiratory tract, particularly in paediatric patients.

Pharmaxis chief executive officer Gary Phillips said the company was “clearly disappointed that Bronchitol cannot yet be made available to patients in the US”.

“The FDA has provided guidance on the necessary measures to gain approval and Pharmaxis will now have a follow up meeting with the FDA,” Mr Phillips said.

“This will be a type A meeting which I expect will take place [by July 2013] and will examine the parameters of an additional clinical trial including how best to incorporate both adult and paediatric patients,” Mr Phillips said.

“At the recent Pulmonary-Allergy Drugs Advisory Committee meeting we received strong support from the US [Cystic Fibrosis] Foundation, leading … clinicians and patients who spoke passionately about the need for Bronchitol,” Mr Phillips said.

“The company remains committed to bringing Bronchitol to [cystic fibrosis] patients in the US and the onus is now on Pharmaxis to work with the FDA to ensure Bronchitol is approved as soon as possible,” Mr Phillips said.

Mr Phillips told Biotech Daily that until the company had the meeting with the FDA it would not know what the regulator would require.

Mr Phillips said that if it was a similar sized trial to the one already conducted it could take up to two years.

Mr Phillips said that Pharmaxis had about $74 million in cash.

Pharmaxis said the FDA had previously granted Bronchitol orphan drug designation for with cystic fibrosis.

In January the FDA’s Pulmonary-Allergy Drugs Advisory Committee refused Pharmaxis market approval application for Bronchitol for cystic fibrosis (BD: Jan 31, 2013).

The Committee voted by 11 votes to three against whether Bronchitol was safe and demonstrated efficacy, criticized the phase III trial data and unanimously opposed marketing approval for patients aged six years and over.

Lodge Partners analyst Marc Sinatra told Biotech Daily at that time that “comments made by the committee throughout the meeting were generally of a critical nature, both on the efficacy and safety side of the equation … [and it was] highly likely that Pharmaxis will have to provide a new trial to win FDA approval”.

In 2011, the European Medicines Agency’s Committee for Medicinal Products for Human Use overturned its previous refusal to grant marketing authorization of Bronchitol for cystic fibrosis allowing the drug for patients aged over 18 years, but requiring a further trial to allow the drug for patients aged six to 18 years (BD: May 25, Jun 27, Oct 24, 2011).

Bronchitol has been approved for cystic fibrosis in adults in Australia, with reimbursement approval in Australia and Europe.

Pharmaxis fell 3.5 cents or 7.1 percent to 46 cents with 2.1 million shares traded.

HEARTWARE INTERNATIONAL

Heartware has raised $US149,126,250 ($A143,374,981) through the placement of 1,725,000 US shares at $US86.45 a share.
Heartware said the underwriters exercised their full option for an additional 225,000 shares to cover over-allotments.
The company said the funds were for working capital and general corporate purposes.
Heartware said that JP Morgan Securities was the sole book-running manager, with Canaccord Genuity, Credit Suisse Securities and Lazard Capital Markets acting as co-managers and Perella Weinberg Partners the independent capital markets advisor.
Heartware was untraded at $2.48.

BIOTRON

Biotron says a 21-patient, phase Ib/IIa trial in Thailand has demonstrated that BIT225 targets HIV replication in monocyte cells in treated patients.
Biotron said that the cells become infected with HIV and were the seeds of hidden HIV pools in patients, setting up long-lived macrophage reservoir cell populations in various sites in the body.
The company said that the trial demonstrated that BIT225 was capable of significantly reducing virus levels in the monocyte cells.
Biotron managing director Dr Michelle Miller said the data was “very encouraging” and could pave the way for a new generation of HIV treatment.
“For the first time we have a potential treatment which may halt the ongoing cycle of infection and re-infection with virus from these long-lived cells,” Dr Miller said. “This is a significant development for our company and has the potential to impact HIV research globally, particularly in terms of treatment in an important HIV reservoir.”
Biotron said that targeting virus reservoirs was the holy grail of current HIV research.
The company said that monocytes were blood cells that became infected with HIV, then moved from blood vessels into different organs such as the liver, lungs, gut and brain, where they matured into macrophages.
Biotron said that HIV replicated at low levels in the infected macrophages, acting as ongoing sources of virus and existing drugs were ineffective in treating HIV in these cells.
The company said that BIT225 was synergistic in-vitro with commonly used anti-retroviral therapies and would potentially be used in conjunction with these treatments.
Biotron said that approved anti-HIV drugs targeted HIV in T-cells and their use was aimed at keeping virus levels in the blood in check and ensuring T-cell counts were in a healthy range, but the treatments did not target underlying viral reservoirs.
The company said that HIV patients enrolled in the study had high virus levels and good CD4+ T cell counts and none had previously received treatment with anti-retroviral drugs and were treated with either BIT225 (400mg; twice daily) or placebo for 10 days.
The company said that further analyses were ongoing and completed safety data was yet to be reviewed, with full results expected to be presented at a later in 2013.
Biotron said that BIT225 was also in development for treatment of hepatitis C virus and that in its recent phase IIa trial, 100 percent of patients with hepatitis C who received BIT225 (400mg) in combination with interferon and ribavirin had undetectable virus levels after 48 weeks.
The company said that a phase II trial of BIT225 in patients co-infected with both HIV and HCV was in progress.
Biotron was up half a cent or 4.55 percent to 11.5 cents with 5.5 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies has begun an intellectual property assertion program in Europe to recover unpaid licence fees relating to its non-coding DNA patents.
Genetic Technologies has initiated two legal actions in the US that have led to a number of licences and revenue (BD: May 26, 2011; Feb 21, 2012).
Today, the company said its Hamburg, Germany lawyers Glawe Delf Moll had begun legal action against the Ingelheim-based Bioscientia Institute for Medical Diagnostics and its Breda, Netherlands-based lawyers AKD had begun a preliminary witness examination against the Boxmeer-based Hendrix Genetics BV.
Genetic Technologies said that consultants were in discussion with several other German laboratories concerning their accrued indebtedness to the company, as well as other entities in Belgium, the Netherlands, Switzerland, Italy, France, Spain and UK.
The company said there were five actions continuing against Agilent Technologies, Bristol-Myers Squibb, Glaxosmithkline, Merial and Pfizer, with suits filed against, and discussions underway with, Genesis Genetics Institute, Medical Diagnostic Laboratories, Reproductive Genetics Institute, Reprogenetics, Genetics and IVF Institute, Prevention Genetics and Genelex Corp.
Genetic Technologies said it had also filed law suits against Natera, Histogenetics, and General Genetics and discussions were being pursued.
Genetic Technologies was up 0.1 cents or 1.3 percent to 7.9 cents.

ANTISENSE THERAPEUTICS

Antisense says it will spend up to $300,000 on a toxicology study for its Chinese joint venture phase IIb study of ATL1102 for multiple sclerosis.
Last year Antisense said it had formed a joint venture with Tianjin International Joint Academy of Biotechnology and Medicine to develop and commercialize ATL1102 for multiple sclerosis, stem cell mobilization and asthma (BD: Feb 29, 2012).
The company said at that time that it would provide access and appropriate licences to the ATL1102 patents and patent applications and related know-how for ATL1102 research and development and commercialization purposes, including data previously generated up to and including the phase II stage of development.
Antisense said in 2012 that the Academy and its investment partners would fund all the agreed development activities.
Today, Antisense said that China contract research organization Pharmaron would conduct the chronic toxicology study by the end of 2013, significantly lowering costs, with the study's data and associated intellectual property rights remaining with Antisense.
Antisense said that the Academy would undertake a stem cell mobilization study at its cost to an agreed cap at their facility in Tianjin, China.
The company said the study would investigate the potential of ATL1102 to release stem cells into the blood when dosed over a short one week period, which would be beneficial for planning future human studies in which the drug would also be dosed acutely.
Antisense said that the joint venture would prepare and submit a clinical trial application for a follow-on human stem cell mobilization study based on previously data.
The company said that the study would use ATL1102 to optimize release of stem cells for their collection from the blood to characterize their potential use in cancer patients to restore immune cells depleted by chemotherapy.
Antisense said that the Academy had agreed an extension to the establishment of the joint venture proposed under the strategic alliance agreement to September 30, 2013.
Antisense was unchanged at 1.1 cents with 1.1 million shares traded.

RESONANCE HEALTH

Resonance says it has an undisclosed multi-year contract with an unnamed European pharmaceutical company for Ferriscan services for a clinical drug trial.
Resonance said that patients in the clinical trial were being treated for iron overload with a new therapy to chelate, or remove, iron from their organs.
The company said that the contract involved the provision of Ferriscan services to a large number of magnetic resonance imaging facilities across several countries.
Resonance said it would provide Ferriscan liver iron concentration measurements for patients enrolled in the study together with a range of project management services.
The company said that its Ferriscan was “considered the international gold standard for the non-invasive measurement of liver iron, replacing the need for patients to have a liver biopsy”.
Resonance said that patients could safely have repeat measurements over the course of their treatment providing a significant benefit to clinical trials.
Resonance was up 0.3 cents or 20 percent to 1.8 cents.

ISONEA

Isonea says it will unveil its Asthmasense cloud monitoring technology at the Asthma Foundation’s conference in Canberra today.
Isonea said the Asthmasense Cloud enabled automatic transfer and storage of asthma tracking data from a ‘smart’ telephone application to a secure cloud-based site, where it could also be viewed on the user’s computer.
The company said that Asthmaense Cloud preserved the asthma event and symptom history in case the user’s telephone was lost, damaged, or exchanged and would enable the user to share their asthma trends with physicians, caregivers or family.
Isonea chief executive officer Michael Thomas said he expected the Asthmasense Cloud to be released to the general public at the end of March 2013, with the Airsonea device to be launched later this year.
Isonea fell 0.1 cents or 1.3 percent to 7.5 cents.