Biotech Daily

Monday April 8, 2013

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: CELLMID UP 13%, PATRYS DOWN 11%**

*** ALLIED HAILS INCREASED PRE-AUTHORIZATION USE OF CARDIOCEL**

*** BIONOMICS UNDERWRITTEN RIGHTS ISSUE RAISES $12.15m OF $16.4m**

*** RESONANCE EXPECTS FDA HEPAFAT-SCAN APPROVAL WITHIN 6 WEEKS**

*** SUDA BUYS NOVADEL NOVAMIST SPRAY FOR $400k, STOCK**

*** M&G GROUP TAKES 12% OF STARPHARMA**

*** CELLMID LOSES JOINT COMPANY SECRETARY ANDREW BALD**

MARKET REPORT

The Australian stock market climbed 0.29 percent on Monday April 8, 2013 with the S&P ASX 200 up 14.1 points to 4,905.5 points.

Ten of the Biotech Daily Top 40 stocks were up, 13 fell, 11 traded unchanged and six were untraded.

Cellmid was the best, up 0.4 cents or 13.3 percent to 3.4 cents with 8.4 million shares traded, followed by Antisense up 11.1 percent to one cent with 3.3 million shares traded.

Viralytics climbed 8.5 percent; Genetic Technologies was up 5.7 percent; Atcor was up 3.45 percent; Prana and Sirtex rose more than two percent; Medical Developments, Mesoblast and Pharmaxis were up more than one percent; with CSL and Resmed up by less than one percent.

Patrys led the falls, down 0.3 cents or 10.7 percent to 2.5 cents with 315,900 shares traded.

Clinuvel lost 7.6 percent; GI Dynamics was down 5.5 percent; both Phosphagenics and Starpharma fell four percent; Neuren and Prima were down more than three percent; Heartware, Living Cell and Nanosonics shed more than two percent; Acrux, Cochlear and Universal Biosensors were down more than one percent; with QRX down 0.4 percent.

ALLIED HEALTHCARE GROUP

Allied Health says five surgeons are actively using, or have Australian Therapeutic Goods Administration pre-market authorization for, Cardiocel to treat congenital heart disease.
Allied said that other surgeons were in the application process to use the Adapt-treated Cardiocel bovine patch through the Authorized Prescriber Scheme.
The company said that Brisbane Mater Hospital paediatric cardiac surgery director Dr Nelson Alphonso had TGA authorization to use Cardiocel for treating and repairing congenital heart defects under the Authorized Prescriber Scheme, joining the Mater's Dr Tom Karl, who was the first to be Scheme approved for Cardiocel use.
Allied regenerative medicine division chief executive officer Bob Atwill told Biotech Daily the scheme "allows surgeons to gain clearance from the hospital ethics committee to use Cardiocel and a request is then made to the TGA for the product, in which the surgeon can see value for patients, but is not yet registered".
Allied said that the University of Melbourne's Prof Christian Brizard and his colleagues had early access to Cardiocel under a trial at a Melbourne based hospital.
Prof Brizard is the director of cardiac surgery at Parkville's Royal Children's Hospital.
The company said that the purpose of the investigator-led clinical study was to expand the access to Cardiocel in Australia.
Allied said that the early access clinical trial scheme would enroll up to 40 congenital heart disease patients.
Allied managing director Lee Rodne said that there were "a number of surgeons in Australia that see the clinical benefits of Cardiocel and a growing number of these have been working within their institutions to find a way to gain early access to Cardiocel".
"With five surgeons now successfully using it in [congenital heart disease] pre-approval to treat and repair these heart defects," Mr Rodne said.
Allied said that congenital heart disease was a leading cause of mortality in infants globally.
The company said that six children were born with congenital heart disease every day in Australia and more than 40,000 were born each year in the US.
"Key opinion leaders in the field of cardiothoracic surgery in Asia Pacific, Europe and US realize Cardiocel is the next logical step in the treatment of [congenital heart disease] patients," Mr Atwill said.
"We now have advisory boards in the three jurisdictions and as soon as possible they will be using Cardiocel in their centers for its anti-calcification profile, regenerative properties and ease of handling," Mr Atwill said.
Allied said that several other Australian surgeons were pursuing access for Cardiocel under the Authorised Prescriber Scheme.
Allied was unchanged at 2.8 cents.

BIONOMICS

Bionomics says it has raised $12,152,757 through applications for 33,757,657 shares at 36 cents a share in its fully underwritten $16.4 million one-for-eight rights issue.
Bionomics said that the shortfall of 11,877,305 shares would be dealt with by the underwriter and lead manager, Bell Potter Securities (BD: Mar 4, 2013).
The company said it received applications for 74 percent of the shares on offer.
Bionomics was unchanged at 37 cents.

RESONANCE HEALTH

Resonance says it has submitted additional information on its Hepafat-Scan diagnostic to the US Food and Drug Administration and expects market clearance within six weeks.
Resonance said that non-alcoholic fatty liver disease was currently diagnosed through liver blood tests and required imaging of the liver to detect excess fat.
The company said the Hepafat-Scan provided a more quantifiable and accurate imaging assessment of the amount of fat in the liver than other tests currently available.
Resonance said that due to the increasing prevalence of fatty liver disease, pharmaceutical companies were working to develop new drug therapies to address the disease and Hepafat-Scan provided a suitable diagnostic test for clinical trials to measure the efficacy of drugs under development.
The company said that fatty liver disease was a significant health care burden in most Western countries and in Australia the most prevalent liver disease was non-alcoholic fatty liver disease, affecting about 5.5 million Australians, including 40 percent of adults aged 50 years and above.
Resonance was untraded at 1.5 cents.

SUDA (FORMERLY EASTLAND MEDICAL SERVICES)

Suda says it will acquire Novadel Pharma's oro-mucosal Novamist platform technology for $400,000, 50,000,000 shares and 10,000,000 options.
Suda said it would acquire intellectual property and inventory relating to the Novamist technology platform and patent portfolio from the Bridgewater New Jersey-based Novadel.
Novadel trades as an over-the-counter stock and was last traded at 0.98 US cents with 120,000,000 shares on offer, implying a market capitalization of $US1,176,000.
Suda said that 50,000,000 shares would be issued on closing and the 10,000,000 unlisted options had an exercise price of five cents by December 31, 2015.
Suda said that the equity component was subject to a limit-on-trading clause.
Suda is developing Artimist as treatment for paediatric malaria (BD: Mar 26, 2013).
The company said that the Novamist technology enabled rapid delivery of drugs into the bloodstream, which could result in a faster onset of action and potential patient benefits in compliance, convenience and safety.
Suda said that spray formulations were a suitable alternative to solid dosage forms as demonstrated by the products already on the market and could deliver drugs into the salivary fluid or on to the mucosal surface of the mouth, making the drug readily available for absorption.
The company said that spray delivery provided life cycle extension for products facing patent expiration as well as new product development opportunities for companies wishing to develop their own brand of a competitor's drug that was approaching expiration of its composition-of-matter patent.
Suda said that Novadel held a broad portfolio of granted patents and pending patents, covering the buccal and mucosal delivery of a wide range of drugs for the central nervous system, erectile dysfunction, pulmonary arterial hypotension, biologically active peptides hormones such as, insulin and cyclosporine.
The company said the patents covered antibiotics, anti-fungals, anti-virals, anti-asthmatics, barbiturates and opioids as well as, polar and non-polar sprays or capsules.
Suda said that the key product in development Duromist was a stable solution of lingual sildenafil, which was the active ingredient in Viagra that had shown preliminary bioequivalence to Viagra tablets in early clinical trials.
Suda was up 0.1 cents or 3.1 percent to 3.3 cents with 1.6 million shares traded.

STARPHARMA

M&G Investment Funds has increased its substantial shareholding in Starpharma from 31,234,957 shares (11.01%) to 34,174,302 shares (12.04%).
The London-based M&G companies first acquired 18,604,651 shares (6.70%) in November 2011 for $19,999,999 or $1.075 a share and have continued increasing their holding (BD: Nov 24, Dec 13, 2011; Mar 22, Jul 3, Nov 23, Dec 11, 2012).
Last year, the M&G Group said it bought 2,700,148 shares between November 22 and December 7, 2012, buying more than 1.5 million shares for prices between $1.02 and $1.14 following the November 29, 2012 share price fall on the news of the failed Vivagel phase III bacterial vaginosis trial (BD Nov 29, Dec 11, 2012).
Today, the M&G Group said it acquired 2,939,345 shares between December 10, 2012 and April 4, 2013 at a range of prices, with the most recent acquisition 250,000 shares for $308,391 or $1.234 a share on April 4, following the company's announcement of positive clinical, but narrowly not statistically significant, phase II trial results for Vivagel for recurrence of bacterial vaginosis.
Starpharma fell 4.5 cents or four percent to $1.08 with 1.1 million shares traded.

CELLMID

Cellmid says that joint company secretary Andrew Bald has resigned effective immediately.
Cellmid said that Nicholas Falzon would continue as company secretary.
Cellmid was up 0.4 cents or 13.3 percent to 3.4 cents with 8.4 million shares traded.