Biotech Daily

Wednesday November 16, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH EVEN: PRANA UP 15.5%, ATCOR DOWN 28%**

*** CSL: 'CSL112 SAFE, REMOVES CHOLESTEROL POST-CARDIAC ARREST'**

*** MACH7 RAISES $9m**

*** ZELDA BACKDOOR IPO RAISES $4m**

*** ATCOR RAISES $1.9m FOR SALES, WORKING CAPITAL**

*** TEXAS CHILDREN'S OKAYS RESAPP KIDS RESPIRATORY TRIAL**

*** PHOSPHAGENICS RECOVERS O-T-C LICENCE; BIOELIXIA SALE**

*** MEDIBIO REQUESTS 'MAJOR CAPITAL RAISING' TRADING HALT**

*** PHORIA, SKINVIEW WIN $25k MCRI BYTES4HEALTH PRIZES**

*** CRYSTAL AMBER TAKES 17.5% OF GI DYNAMICS**

*** RESONANCE APPOINTS DR TRAVIS BARONI DIRECTOR**

MARKET REPORT

The Australian stock market edged up 0.03 percent on Wednesday November 16, 2016 with the ASX200 up 1.5 points to 5,327.7 points. Fifteen of the Biotech Daily Top 40 stocks were up, 15 fell and 10 traded unchanged.

Prana was the best, up 0.9 cents or 15.5 percent to 6.7 cents with 1.1 million shares traded. Osprey climbed 7.3 percent; Dimerix and Living Cell were up more than six percent; Benitec improved 4.8 percent; Acrux was up three percent; Actinogen, Compumedics, IDT, Orthocell and Prima rose more than two percent; with Clinuvel, Cochlear, Nanosonics, Sirtex and Viralytics up by less than one percent.

Atcor led the falls on a $1.9 million placement at a 35 percent discount to last night's close, down 2.8 cents or 28.0 percent to 7.2 cents with 10.3 million shares traded. Psivida lost 9.1 percent; Impedimed shed 6.7 percent; Medical Developments was down 5.9 percent; both Ellex and Mesoblast fell 4.76 percent; Admedus, Bionomics, CSL, Cyclopharm, Factor Therapeutics and Uscom shed more than two percent; Airxpanders, Anteo, Genetic Signatures and Polynovo were down more than one percent; with Resmed down 0.3 percent.

CSL

CSL says that phase IIb safety and proof-of-mechanism study shows that CSL112 is safe, well-tolerated and removes plaque cholesterol following myocardial infarction.

CSL said that the data from the 'Aegis-I' trial of CSL112, an apolipoprotein A-I infusion therapy was presented at the American Heart Association meeting in New Orleans, Louisiana on November 15, 2016.

The company said that CSL112 was being developed "to reduce the high incidence of early recurrent cardiovascular events that frequently occur in the weeks to months following a heart attack, most commonly due to additional rupture of vulnerable atherosclerotic plaque".

CSL said that the results had been published onlineina an article entitled 'Safety and Tolerability of CSL112, a Reconstituted, Infusible, Plasma-Derived Apolipoprotein A-I, After Acute Myocardial Infarction: The AEGIS-I Trial (ApoA-I Event Reducing in Ischemic Syndromes I)' in the AHA's journal Circulation, with an abstract available at: http://circ.ahajournals.org/content/early/2016/11/11/CIRCULATIONAHA.116.025687.

The company said that the Aegis-I study met its co-primary safety endpoints, showing that CSL112 did not cause significant changes in liver or kidney function and demonstrated that it was well-tolerated when administered in the post myocardial infarction or heart attack setting.

CSL said that the study provided confirmation of CSL112's mechanism of action, cholesterol efflux enhancement, as demonstrated by an immediate, up to four-fold increase in cholesterol efflux capacity, compared to baseline.

The company said that "by producing an immediate and profound enhancement of cholesterol efflux capacity, which is the removal of cholesterol from the plaque in the arteries, CSL112 may rapidly stabilize additional lesions at risk of rupture thereby reducing the high rate of recurrent events following a heart attack".

CSL Behring cardiovascular clinical therapeutic area head Dr Larry Deckelbaum said the company was "highly encouraged by the impressive results of this clinical study demonstrating that CSL112 significantly increases cholesterol efflux capacity in patients who have suffered a heart attack, with no significant changes to liver or kidney function".

"The Aegis-I results support continued planning for phase III to determine whether increasing cholesterol efflux capacity with CSL112 translates into improved cardiovascular outcomes," Dr Deckelbaum said.

CSL said that in the US alone there were about 750,000 cardiac arrests every year and for the patients who survived, the risk was not over.

The company said that about one in five heart attack survivors would experience a recurrent cardiovascular event within one year and most of those events occur very early, with about half within the first month.

CSL said that recurrent events were associated with worse clinical outcomes.

The company said that by rapidly removing cholesterol from plaque following a heart attack, CSL112 might help stabilize dangerous lesions in the arteries that could otherwise erupt and cause another cardiovascular event.

CSL said that CSL112 was a novel formulation of plasma-derived apoA-I, the primary functional component of high density lipoprotein (HDL) and was being developed by CSL Behring, in collaboration with the parent company, CSL.

The company said that CSL112 was reconstituted to form HDL particles suitable for intravenous infusion and studies had shown that infusion of CSL112 rapidly elevates markers of cholesterol efflux capacity, a process by which excess cholesterol was removed from plaque and transported to the liver for elimination from the body.

CSL fell $2.31 or 2.3 percent to $99.14 with 1.3 million shares traded.

MACH7 TECHNOLOGIES

Mach7 says it has raised $9 million through a placement to sophisticated and institutional investors at four cents a share.
Mach7 said that the placement included $600,000 for shares from directors and senior management of the Company.
The company said that the Melbourne-based JM Financial Group Ltd was the lead manager for the placement.
Mach7 said that $6.9 million before costs would be used for investment into sales and marketing resources, customer support services, new product development, and working with the $2.1 million balance used to retire debt.
Mach7 was up 0.1 cents or 2.5 percent to 4.1 cents.

ZELDA THERAPEUTICS (FORMERLY GLENEAGLE GOLD)

Zelda says it has raised the $4 million maximum allowed under its prospectus offering at 2.5 cents a share.
Zelda said that the funds were to continue with pre-clinical research and development activities, fund human clinical trials and expand the management and advisory team.
The company said its ASX ticker code had changed from GLN to ZLD and it would proceed with the formal re-admission process with the Australian Securities Exchange and provide an update on the indicative listing date “in due course”.
In August, Zelda said it would develop sublingual and topical marijuana treatments for insomnia, acne and glioblastoma (BD: Aug 24, 2016).
Zelda executive director Dr Stewart Washer told Biotech Daily in August that the San Francisco, California-based Aunt Zelda was the major shareholder of Zelda Therapeutics with about 30 percent, with Harry Karelis as executive chairman and directors including CPS Securities stock broker Jason Peterson and Aunt Zelda founder Mara Gordon.
Zelda, then Gleneagle Gold, last traded at 2.5 cents post-consolidation.

ATCOR MEDICAL

Atcor says it has raised $1.9 million in a placement at 6.5 cents a share to sophisticated and institutional shareholders, including a new US institutional shareholder.
Atcor said the placement included participation by its directors for $130,000 in shares, subject to shareholder approval.
The company said the funds would be used to accelerate the rollout of its clinical market strategy to capitalize on the US common procedural terminology (CPT-1) code allowing doctors to claim reimbursement for using the Sphygmocor central blood pressure an arterial stiffness test, and to provide additional working capital.
Atcor said it was completing a pilot sales roll-out in four areas and would expand its sales force prioritizing areas with the highest percentage of insurers covering the test.
The company said that 42 percent of the 290 million US insured lives were reimbursed for the Sphygmocor test, including seven of the 12 Medicare regions.
Atcor said it had reduced non-sales costs by about $1 million and cash requirements for the year to June 30, 2017 were forecast to decrease by about 60 percent.
Atcor chief executive officer Duncan Ross said the company was “making good progress implementing our refined sales strategy to focus on local health systems, known as integrated delivery networks, and multi-doctor private specialist practices”.
The company said that Taylor Collison was the lead manager for the placement.
Atcor fell 2.8 cents or 28 percent to 7.2 cents with 10.3 million shares traded.

RESAPP HEALTH

Resapp says the Baylor College of Medicine and Texas Children's Hospital has approved its pivotal paediatric, respiratory disease Smartcough-C study.

Resapp said that the principal investigator at the Houston, Texas-based Baylor College of Medicine and Texas Children's Hospital would be paediatric emergency medicine professor Prof Esther Maria Sampayo.

Last week, Resapp said that Boston's Massachusetts General Hospital approved the large-scale, pivotal, prospective, paediatric, respiratory disease Smartcough-C study (BD: Nov 11, 2016).

The company said the study was a multi-site, double-blind study evaluating the efficacy of its Resappdx software application for the diagnosis of childhood pneumonia and other respiratory conditions from cough sounds.

Resapp said the primary endpoint was the diagnosis of pneumonia with secondary endpoints upper respiratory tract infection, croup, bronchiolitis and asthma.

Resapp fell one cent or 2.5 percent to 39 cents with 4.1 million shares traded.

PHOSPHAGENICS

Phosphagenics says that the use and ownership of its over-the-counter pharmaceutical applications for tocopheryl phosphate mixture (TPM) be returned.

Phosphagenics said that the American Arbitration Association made the determination in relation to formal arbitration between Phosphagenics and Prophase Labs Inc over their 2010 Phusion Laboratories LLC joint venture to develop a range of over-the-counter products using the TPM technology.

Phosphagenics chief executive officer Dr Ross Murdoch told Biotech Daily that the Elixia and Bioelixia cosmetic range was not involved in the original joint venture, but became entangled in the litigation.

Dr Murdoch said that the joint venture did not succeed and was subsequently dissolved, but the on-going litigation meant that the company was unable to sell the cosmetic range.

Phosphagenics said that Prophase claimed that Phosphagenics had breached the over-the-counter (OTC) licence granted to the joint venture entity and the joint venture operating agreement and began the legal action.

The company said that both parties sought damages during the arbitration, but no cash damages were awarded to either party.

Phosphagenics said that all of its legal costs associated with the Prophase arbitration proceedings had been paid.

In a media release Dr Murdoch said it was "a good result for Phosphagenics".

"We believe the potential OTC pharmaceutical applications for TPM are significant and thus retaining full ownership of this licence represents a valuable opportunity for Phosphagenics' shareholders," Dr Murdoch said. "We are now free to move forward with the sale of the Bioelixia brand which has been on hold pending this result."

"We hope we can conclude a sale in the near future," Dr Murdoch said.

Phosphagenics was up 0.3 cents or 11.1 percent to three cents.

MEDIBIO

Medibio has requested a trading halt "pending the announcement of a major capital raising".

Trading will resume on November 18, 2016 or on an earlier announcement.

Medibio last traded at 47 cents.

MURDOCH CHILDRENS RESEARCH INSTITUTE

The Murdoch Childrens Research Institute says that Phoria and Skinview have won the Bytes4health program with $25,000 each to develop their technologies.
The Institute said that Bytes4health was supported by innovation company Curve Tomorrow and winners announced by the Federal Minister for Health Sussan Ley.
The MRCI said that the two winners were selected from 10 finalists to develop their health technology products, which would ultimately benefit the health and well-being of seriously ill children and the wider population.
The Institute said that the winners would have the opportunity to work closely with research and clinical leaders at the Murdoch Childrens Research Institute.
MCRI said that Melbourne's Phoria was a virtual reality company which had designed a custom virtual reality experience for children in hospital and its Dream3D allowed patients to choose their own adventures while enabling researchers to validate the clinical benefits of using virtual reality and improve the well-being of long-stay, chronically ill children.
The Institute said that Hobart's Skinview had developed a disposable device that clipped to a mobile telephone, turning it into a digital dermatoscope to examine skin lesions and diagnose and monitor paediatric skin conditions.

GI DYNAMICS

The Crystal Amber Fund says it has increased its substantial shareholding in GI Dynamics from 77,355,813 shares (16.27%) to 83,060,094 shares (17.47%).
The London and St Peter Port, Guernsey Island-based Crystal Amber Fund said that between September 20 and November 14, 2016 it acquired 5,704,281 shares for $131,072 or an average price of 2.3 cents a share.
The company's website said it was listed on London's Alternative Investment Market.
GI Dynamics was untraded at 2.8 cents.

RESONANCE HEALTH

Resonance says it has appointed Dr Travis Baroni as an independent non-executive director, effective from November 25, 2016, the day after the annual general meeting.
Resonance said that Dr Baroni had experience across industrial research, commercialization of technology, asset valuations and investment banking services.
The company said that Dr Baroni had managed innovation development and technology strategy in a large company as well as being an active investor in early stage investments.
Resonance was untraded at 2.3 cents.