Biotech Daily

Tuesday February 9, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ATCOR UP 9%, NEUREN DOWN 12%**

*** IMPEDIMED $75m FOR L-DEX, HEART TEST; PLAN FOR $7.5m MORE**

*** SWINBURNE TESTS WEARABLE DEVICES FOR MEDIBIO MENTAL HEALTH**

*** MELBOURNE UNI TRIALS BRAIN-MACHINE 'STENTRODE' IN SHEEP**

*** BIOTA STARTS PHASE II BTA074 ANO-GENITAL WARTS TRIAL**

*** ACTINOGEN RECEIVES $1.3m FEDERAL R&D TAX REFUND**

*** ADMEDUS LOSES DIRECTOR PETER TURVEY**

*** PSIVIDA LOSES DIRECTOR PETER SAVAS**

MARKET REPORT

The Australian stock market lost 2.88 percent on Tuesday February 9, 2016 with the ASX200 down 143.3 points to 4,832.1 points.

Seven Biotech Daily Top 40 stocks were up, 25 fell, six traded unchanged and two were untraded. All three Big Caps fell.

Atcor was the best, up 1.5 cents or 8.6 percent to 19 cents with 110,000 shares traded.

Tissue Therapies climbed five percent; Anteo 4.5 percent; with Antisense, Benitec, Medical Developments and Reva up more than one percent.

Neuren led the falls, down 1.3 cents or 11.8 percent to 9.7 cents with 4.3 million shares traded, followed by Impedimed down 10.6 percent to 93 cents with 1.5 million shares traded.

Living Cell lost 8.8 percent; Osprey and Starpharma fell more than seven percent; Prana was down 6.4 percent; Cellmid, Compumedics, Mesoblast, Opthea, Orthocell and Prima were down more than four percent; Acrux, Admedus, Bionomics and Pro Medicus were down three percent or more; Cochlear, CSL, Nanosonics, Oncosil, Psivida, Universal Biosensors and Viralytics shed more than two percent; with Actinogen, Biotron, Polynovo, Resmed and Sirtex down by one percent or more.

IMPEDIMED

Impedimed says it has expects to raise $75,000,000 at 95 cents a share to fund sales of its L-Dex lymphoedema test and develop a chronic or congestive heart failure test.

Impedimed said commitments from sophisticated and professional investors would be completed in two tranches with 44,062,855 shares to be issued under its 15 percent placement capacity, with 34,884,513 shares subject to shareholder approval.

The company said that Canaccord Genuity (Australia) was the sole lead manager and book-runner and the funds would be used to expand sales and marketing of the L-Dex system, allow for balance sheet flexibility and working capital expansion to drive additional L-Dex growth and pursue the chronic, or congestive, heart failure business.

Cannacord senior analyst Dr Matthijs Smith told Biotech Daily that the new device for heart failure would be an early warning system aimed at letting the patient and their physician know that heart failure was progressing and aimed to intervene before hospital readmission became necessary.

“The new device is a simple measure of bio-impedance through the body, tested through the hands and feet placed on sensors, and providing data that gives an early warning of the progress of heart failure,” Dr Smith said.

“It allows the opportunity for early intervention,” Dr Smith said.

Dr Smith said that measuring fluid in the lungs through bio-impedance was “a huge opportunity” and said that with 1.5 million class III cardiac patients in the US and charging $US60 a month per patient for daily routine testing would result in a $US90million a month addressable market.

Dr Smith said that an weight-scale-based system was charging about $US150 a month.

Impedimed said that development path for the diagnostic system would be through the US Food and Drug Administration 510(k) process and it would conduct a clinical trial in congestive heart failure.

The company said that a share purchase plan, capped at $7.5 million, would offer investors at the record date of February 8, 2016 the opportunity to buy up to $15,000 in shares at 95 cents a share.

Impedimed chief executive officer Richard Carreon said the raising “provides us with significant balance sheet strength to drive our business”.

Impedimed fell 11 cents or 10.6 percent to 93 cents with 1.5 million shares traded.

MEDIBIO

Medibio says that Swinburne University’s Software Innovation Lab will evaluate wrist-based wearable devices for its heart rate-based mental health test.

Medibio said that the Melbourne-based Swinburne laboratory would examine the data quality and suitability of wrist-based wearable devices, including evaluating the Apple Watch, Fitbit Surge, Samsung Gear S2 and the Jawbone UP3, for potential integration and connectivity to its mental health platform, including its corporate stress products.

The company said there was “an accelerating trend for health insurance, life insurance, wellness providers and corporate workplaces to provide wearables for their members and employees as part of general wellness programs”.

Medibio said that evaluation was a prerequisite for the delivery of a consumer stress mobile telephone application and it expected to complete the first stage in March 2016.

The company said that in the US one in 10 adults owned a fitness tracker and revenue was predicted to increase by 40 percent as consumers adopted smaller wearable technologies that can provide the same applications.

Medibio fell one cent or four percent to 24 cents.

UNIVERSITY OF MELBOURNE, FLOREY INSTITUTE OF NEUROSCIENCES, RMH

The University of Melbourne says a minimally invasive brain-machine interface, gives people with spinal cord injuries the hope to walk with the power of thought.

In a media release from the University, the Florey Institute of Neurosciences and the Royal Melbourne Hospital said that a stent-based electrode, or 'stentrode', was implanted within a blood vessel next to the brain in sheep, recording the type of neural activity shown in pre-clinical trials to move limbs through an exoskeleton or to control bionic limbs.

The media release said that the small paperclip sized device would be implanted in the first in-human trial at the Royal Melbourne Hospital in 2017, with participants selected from the Austin Health Victorian Spinal Cord Service.

The research, entitled 'Minimally invasive endovascular stent-electrode array for high-fidelity, chronic recordings of cortical neural activity' was published in Nature Biotechnology and showed the device was "capable of recording high-quality signals emitted from the brain's motor cortex, without the need for open brain surgery".

An abstract is at: http://www.nature.com/nbt/journal/vaop/ncurrent/full/nbt.3428.html.

Principal author and Royal Melbourne Hospital neurologist as well as Florey and University of Melbourne research fellow Dr Thomas Oxley said the stentrode was "revolutionary".

"The development of the stentrode has brought together leaders in medical research from the Royal Melbourne Hospital, the University of Melbourne and the Florey Institute of Neuroscience and Mental Health," Dr Oxley said.

Dr Oxley said that 39 academic scientists from 16 departments were involved in the development of the stentrode.

"We have been able to create the world's only minimally invasive device that is implanted into a blood vessel in the brain via a simple day procedure, avoiding the need for high risk open brain surgery," Dr Oxley said.

"Our vision, through this device, is to return function and mobility to patients with complete paralysis by recording brain activity and converting the acquired signals into electrical commands, which in turn would lead to movement of the limbs through a mobility assist device like an exoskeleton," Dr Oxley said. "In essence this a bionic spinal cord."

The University said that stroke and spinal cord injuries were the leading causes of disability, affecting one in 50 people and there were 20,000 Australians with spinal cord injuries and about 150,000 Australians left severely disabled after stroke.

Co-principal investigator and University of Melbourne biomedical engineer Dr Nicholas Opie said the concept was similar to an implantable cardiac pacemaker, using electrical interaction with tissue, using sensors inserted into a vein, but inside the brain.

"Utilising stent technology, our electrode array self-expands to stick to the inside wall of a vein, enabling us to record local brain activity," Dr Opie said.

"By extracting the recorded neural signals, we can use these as commands to control wheelchairs, exoskeletons, prosthetic limbs or computers," Dr Opie said.

"In our first-in-human trial, that we anticipate will begin within two years, we are hoping to achieve direct brain control of an exoskeleton for three people with paralysis," Dr Opie said.

"Currently, exoskeletons are controlled by manual manipulation of a joystick to switch between the various elements of walking: stand, start, stop, turn," Dr Opie said. "The stentrode will be the first device that enables direct thought control of these devices."

Florey neuro-physiologist Prof Clive May said the data from the pre-clinical study showed the implanted device was safe for long-term use and it had recorded brain activity "over many months [and] the quality of recording improved as the device was incorporated into tissue".

BIOTA PHARMACEUTICALS

Biota says the first of 210 patients has been dosed in a phase II trial of BTA074 for condyloma, or ano-genital warts, caused by human papillomavirus types 6 and 11.

Biota said that the double-blind, randomized, placebo-controlled trial would evaluate the safety, tolerability and efficacy of topical BTA074 five percent gel in male and female patients.

Biota chief executive officer Dr Joseph Patti said that “currently approved topical treatments for condyloma lack consistent efficacy and cause a considerable amount of undesirable local skin reactions, such as erosions and oedema, often leading to the need to stop treatment”.

“With this larger phase II study, we hope to further validate the clinical activity of BTA074 seen in its earlier phase II trial, which showed evidence of overall clearance and a benign side effect profile,” Dr Patti said.

“We now have three direct-acting antiviral programs in the clinic, each of which has the potential to help patients by attacking the root cause of their viral infections,” Dr Patti said.

Biota said that BTA074 was “a potent and selective inhibitor of the interaction between two viral proteins from HPV6 and HPV11” and was designed to prevent human papillomavirus (HPV) DNA replication.

The company said that patients would be randomization at two active to one placebo and would be dosed twice daily topically for up to 16 weeks.

Biota said the primary efficacy objective was to determine the complete clearance rate for baseline ano-genital warts from the beginning of therapy to the end of treatment, with secondary efficacy endpoints including assessments of clearance and wart area reduction for both baseline warts and post-baseline emergent warts.

The company said that condyloma infections from human papillomavirus were the most frequent viral sexually transmitted disease in adults worldwide with about one to two percent of sexually active adults between the ages of 15 to 49 in the US developing condyloma as the primary clinical manifestation of human papillomavirus infection.

Biota said that currently treatments were ablative or destructive therapies, which could be painful, cause scarring and lead to sexual dysfunction; and topical therapies, which were associated with mucosal toxicities manifesting as erosions and ulcerations.

Biota said that a significant limitation was a high incidence of recurrence.

Last night on the Nasdaq, Biota fell six US cents or 3.97 percent to $US1.45 ($A2.06 equivalent to 25.7 cents before it departed the ASX) with 56,371 shares traded.

ACTINOGEN

Actinogen says it has received $1,321,732 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Actinogen said the rebate related to research and development expenditure for the year to June 30, 2015.

Actinogen fell 0.1 cents or 1.8 percent to 5.4 cents.

ADMEDUS

Admedus says that independent non-executive director Peter Turvey has resigned “due to other commitments”, effective from February 8, 2016.

Admedus said that Mr Turvey had been a director for three years and was head of the audit and risk committee.

Admedus fell two cents or 3.1 percent to 63 cents.

PSIVIDA

Psivida says that director Peter Savas resigned effective from February 5, 2016.
Psivida said that Mr Savas joined the board in 2008 and had served as a member of the audit and compliance and governance and nominating committees.
In its filing to the US Securities And Exchange Commission Psivida said that Mr Savas' resignation was "not due to a disagreement with the company, the board or management on any matter relating to the company's operations, policies or practices".
Psivida fell 13 cents or 2.7 percent to $4.70.