



# Biotech Daily

Friday June 7, 2013

*Daily news on ASX-listed biotechnology companies*

- \* **ASX DOWN, BIOTECH UP: NEUREN UP 7%  
GENETIC TECHNOLOGIES, VIRALYTICS DOWN 8%**
- \* **FDA APPROVES IMPEDIMED L-DEX U400 AS LYMPHOEDEMA TOOL**
- \* **PHARMAXIS CEO GARY PHILLIPS STARTS ON \$388k**
- \* **CALZADA REQUESTS CAPITAL RAISING TRADING HALT**
- \* **UNIVERSAL BIOSENSORS WINS VICTORIA MANUFACTURING AWARD**
- \* **COCHLEAR, SUNSHINE HEART WIN AUSTRALIAN DESIGN AWARDS**

## MARKET REPORT

The Australian stock market fell 0.91 percent on Friday June 7, 2013 with the S&P ASX 200 down 43.5 points to 4,737.7 points.

Seventeen of the Biotech Daily Top 40 stocks were up, seven fell, 10 traded unchanged and six were untraded. All three Big Caps fell.

Neuren was the best, up 0.4 cents or 7.1 percent to six cents, with 6.6 million shares traded.

Allied Health, Bionomics and GI Dynamics climbed more than four percent; Impedimed, Patrys and Pharmaxis were up more than three percent, Acrux, Living Cell and QRX rose more than two percent; Anteo, Atcor and Sirtex were up more than one percent; with Heartware, Medical Developments, Mesoblast and Reva up by less than one percent.

Genetic Technologies and Viralytics led the falls, both down eight percent to 9.2 and 23 cents, respectively, with 55,923 and 150,010 shares traded, respectively.

Benitec lost 7.7 percent; Phosphagenics fell 6.9 percent; Avita fell 4.8 percent; Cochlear and Nanosonics were down more than one percent; with CSL, Resmed and Starpharma down by less than one percent.

## IMPEDIMED

Impedimed says the US Food and Drug Administration has provided '510(k)' clearance of a revised Indications for Use Statement for its L-Dex U400 lymphoedema diagnostic. Impedimed said that the revision removes the sentence, "the device is not intended to diagnose or predict lymphoedema of the extremity".

The company said that the revised clearance "clarifies the use of the L-Dex U400 as an aid to the clinical assessment of unilateral lymphoedema of the arm and leg in women and the leg in men".

Impedimed chief executive officer Richard Carreon told Biotech Daily that the new indications statement was clearer, describing the L-Dex U400 as "a bioimpedance spectroscopy device for use on adult human patients, utilizing impedance ratios that are displayed as an L-Dex ratio that supports the measurement of extracellular fluid volume differences between the limbs and is presented to the clinician on an L-Dex scale as an aid to their Clinical assessment of unilateral lymphedema of the arm and leg in women and the leg in men".

Mr Carreon said the clearance "removes one of the key roadblocks identified in our recent investor presentation".

"This is an important achievement for the company allowing us to accelerate our clinical and reimbursement initiatives," Mr Carreon said.

The FDA website said that a 510k pre-market submission needed to "demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device ... that is not subject to [pre-market approval]".

Impedimed was up 0.2 cents or 3.2 percent to 6.5 cents.

## PHARMAXIS

Pharmaxis says chief executive officer Gary Phillips will have a 15.95 percent base pay rise to \$388,000 and 7.9 million performance rights will be granted to 20 key employees. Pharmaxis said the measures were "designed to retain and 'incentivise' staff remaining with the company".

Pharmaxis chairman Malcolm McComas said the flattened management structure meant that Mr Phillips would retain most of his former responsibilities as chief operating officer. The Pharmaxis 2012 annual report said that for the year to June 30, 2012, former chief executive officer Dr Alan Robertson was paid a base salary of \$423,521 and received a total of \$506,021, while the then chief operating officer Mr Phillips was paid a base salary of \$334,632 and received \$423,722.

Today, Mr McComas said the board decided "to use performance rights to provide short term retention incentives and medium term performance bonuses to key staff and to align performance to the major business transforming milestones ... over the next two years".

Mr McComas said the criteria for the vesting of performance rights would be "an equal weighting of corporate and personal objectives, with the former focussing on partnering Bronchitol, reducing the net cash burn and increasing sales of Bronchitol."

Pharmaxis said Mr Phillips would have a base salary of \$388,000 a year with an additional nine percent compulsory superannuation and short term incentives of up to 30 percent of base salary and that subject to shareholder approval, Mr Phillips would be granted two million performance rights, with a zero exercise price for Pharmaxis shares, vesting in three tranches, subject to corporate and personal objectives.

Pharmaxis said it would grant 7.9 million performance rights to 20 employees on the same conditions.

Pharmaxis was up 0.5 cents or 3.6 percent to 14.5 cents with 1.5 million shares traded.

## CALZADA

Calzada has requested a trading halt “pending an announcement regarding a capital raising”.

Trading will resume on June 12, 2013 or on an earlier announcement.

Separately, Calzada published an updated ‘investor overview’ reviewing its Polynovo and Metabolic assets.

The presentation said that Calzada had \$2.9 million in cash with a further \$750,000 research and development tax incentive expected by October 2013.

The company said that it had an annual cash burn, net of the research and development tax incentive, of about \$2.5 million a year.

Calzada said that most of the funds were being spent on clinical trials and development of Polynovo’s Novosorb biodegradable wound treatment, with a “low cost strategy adopted to generate shareholder value” from Metabolic’s AOD9604, amounting to about 10 percent of Calzada’s costs.

The presentation said that Monash University and AOD9604 inventor Prof Frank Ng owned about four percent of Calzada, with senior management holding a further nine percent and the Perth, Western Australia-based Merchant Funds Management holding 19.6 percent.

Calzada last traded at eight cents.

## VICTORIA GOVERNMENT, UNIVERSAL BIOSENSORS

Universal Biosensors has been presented with a ‘Technology in Manufacturing Award’ at the Victoria Government’s Manufacturing Hall of Fame awards.

The Victoria Government said the award were for the State’s “most inventive, productive and resilient manufacturers”.

Victoria’s Minister for Manufacturing David Hodgett said the awards went to companies “whose creative solutions to manufacturing challenges have identified innovative pathways for a generation of new manufacturers to follow”.

“The awards, now in their thirteenth year, celebrate manufacturing excellence in Victoria,” Mr Hodgett said.

“Over that time the awards have acknowledged the achievements of 131 innovative companies, added 26 outstanding individuals to the honor roll and recognized 10 young manufacturers of the year,” Mr Hodgett said.

Universal Biosensors chief executive officer Paul Wright said his company was “extremely proud to receive this award and thank the Victorian Government for their support and encouragement over many years”.

“Our world-class manufacturing facility in Rowville has solidly anchored our business in Victoria and provides an important platform for future growth,” Mr Wright said.

Universal Biosensors said that the Technology in Manufacturing award recognized companies that embraced enabling and emerging technologies within their manufacturing operations.

The company said it was “a leading player in the point-of-care diagnostics market” and had partnerships with Siemens Healthcare Diagnostics and Johnson & Johnson’s Lifescan, for its core technology of disposable biosensor test strip which used its electrochemical sensors to test for components in the blood.

Universal Biosensors was unchanged at 65 cents.

## COCHLEAR, SUNSHINE HEART

Cochlear and Sunshine Heart have been awarded Australian International Design Awards in the Medical and Scientific category.

Sunshine Heart said that, along with contract development partners, Design + Industry and Hydrix Services, collectively submitted an award application for its second-generation C-Pulse driver in March, with the final awards presented in Sydney on May 30, 2013.

The company said the Australian International Design Awards program was the country's longest running and most prestigious design recognition program with a 55-year history and this year's competition included more than 250 entries across 15

The Australian International Design Awards website said that Cochlear won awards for its Nucleus CR110 Remote Assistant Fitting which allows hearing implant recipients to make adjustments and optimize sound for their specific hearing needs without the need for returning to the clinic, or use of a wired computer system and for its Nucleus CR120 Intraoperative Remote Assistant, which measures neural responses to create a hearing profile for immediate hearing, giving surgeons and their supporting teams confidence that the implant is fully functional.

Cochlear fell 95 cents or 1.7 percent to \$55.65 with 484,891 shares traded.

On the Nasdaq last night Sunshine Heart fell seven US cents or 1.25 percent to \$US5.55.