# Biotech Daily

Thursday February 9, 2012

*Daily news on ASX-listed biotechnology companies*

*** ASX, BIOTECH DOWN: ANTISENSE UP 5%, PSIVIDA DOWN 10%**

*** ANTISENSE: PHASE II ATL1103 TRIAL, NEW PATENT, DEAL CLOSER**

*** BIODIEM LICENCES LAIV TO CHANGCHUN BCHT**

*** PATRYS COMPLETES PHASE I PAT-SM6 TREATMENT**

*** SUNSHINE HEART RAISES $2.1m FOR NASDAQ LISTING**

*** IMPEDIMED INCREASES US COVERED LIVES, REGISTERS 1st PATIENT**

*** BPH'S CORTICAL EARNS WA VOUCHER**

*** IMMURON REBUTS PALADIN 'MISINFORMATION'**

*** LA JOLLA COVE EXITS VIRALYTICS; TAKES 10% OF BONE**

*** AVITA PASSES ALL QUALITY AUDITS**

*** OBJ PLEADS SCHULTZ TO ASX 28% QUERY**

## MARKET REPORT

The Australian stock market slipped 0.18 percent on Thursday February 9, 2012 with the S&P ASX 200 down 7.8 points to 4282.9 points. Eight of the Biotech Daily Top 40 stocks were up, 18 fell, nine traded unchanged and five were untraded. All Big Caps were up.

Antisense was the best, up 0.1 cents or 5.3 percent to two cents with 34 million shares traded.

Neuren and Prana climbed more than three percent; Bionomics rose 2.2 percent; CSL was up 1.2 percent; with Cochlear, Mesoblast, Pharmaxis, QRX, Resmed and Starpharma up by less than one percent.

Psivida led the falls, down 12 cents or 9.8 percent to $1.11 with 4,795 shares traded, followed by Cellmid down 7.7 percent to 1.2 cents with 1.3 million shares traded.

Clinuvel lost 5.85 percent; Impedimed fell 4.7 percent; Allied Health, Avita, Biota and Genetic Technologies were down more than three percent; Anteo, Heartware, Patrys and Prima shed more than two percent; Acrux, Nanosonics, Sirtex, Tissue Therapies and Universal Biosensors were down more than one percent; with Reva down 0.9 percent.

ANTISENSE THERAPEUTICS

Antisense says growth hormone receptor-targeting drug ATL1103 is progressing on a range of fronts including its phase II trial, a cancer indication and a potential deal.

Antisense said the phase I trial demonstrated safety and tolerability as well as a preliminary indication of the drug's pharmacological activity with the reduction of serum IGF-I and other markers in volunteers after three weeks of dosing (BD: Dec 7, 2012).

The company said the phase II study of ATL1103 in patients with the growth disorder acromegaly would assess safety and efficacy over three months and was expected to begin by July 2012 with interim results available by July 2013.

Antisense said it had appointed a scientific advisory group specializing on growth hormone receptor and IGF-I related diseases to oversee the development of ATL1103, including University of California Los Angeles' Prof Pinchas Cohen, the University of Melbourne's Prof Albert Frauman, the University of Queensland's Prof Michael Waters, Melbourne's Royal Children's Hospital's Prof George Werther and Cedars-Sinai Medical Centre, Los Angeles' Dr Vivien Bonert.

Antisense said that the unnamed pharmaceutical company interested in ATL1103 in December 2011 was undertaking "more comprehensive due diligence" and had been supplied with an expanded package of additional data and intellectual property.

The company said that as part of the process it expected "to receive valuable feedback from this experienced drug development pharmaceutical company on the clinical development and commercialization plans for ATL1103".

Antisense said that as part of the ATL1103 phase I trial, Prof Cohen and his US colleagues would undertake a preliminary cancer experimental program.

The company said that the cancer marker assays, in-vitro mitogenic and apoptotic assays, conducted using serum samples from phase I trial subjects showed the level of effect was too subtle for detection, but Prof Cohen believed that further analysis was warranted, with the phase II study providing a more substantial reduction in serum IGF-I based on the longer and potentially higher doses in the phase II trial.

The company said that the expected synergistic effect of reducing serum IGF-I and inhibiting growth hormone receptor had shown promise in preclinical models and could prove valuable in human patients.

Antisense said that ATL1103 might also be uses in combination with Pfizer's Somavert, marketed drug for acromegaly, with the combination adding to ATL1103's commercial prospects as a monotherapy.

The company said that data from the phase I ATL1103 trial, including its specific effect in reducing growth hormone binding protein levels supported the potential for synergistic clinical benefits from the use of ATL1103 in combination with Somavert.

The combination could allow Somavert to be used at lower/less frequent doses in acromegaly treatment (currently Somavert requires daily injection), thereby reducing treatment costs and improving patient compliance.

The combination of the two drugs could also potentially open up other disease applications such as some cancers where a more significant reduction in IGF-I may be required.

A provisional US patent entitled 'Combination therapy' had been lodged seeking protection for the use of ATL1103 and Somavert in combination until 2033.

Antisense chief executive officer Mark Diamond said the company was "excited with the development and commercialization progress made on ATL1103 and we look forward to reporting on these activities as they continue to advance".

Antisense was up 0.1 cents or 5.3 percent to two cents with 34 million shares traded.

## BIODIEM

Biodiem says that it has licenced its live attenuated influenza virus vaccine technology to the China-based Changchun BCHT Biotechnology Co.

Biodiem chief executive officer Julie Phillips told Biotech Daily that the terms of the deal were confidential but were in line with industry standards.

Biodeim said the live attenuated influenza virus (LAIV) vaccine technology licence was for the Chinese private sector market for pandemic and seasonal influenza vaccines made using an egg-based production method.

The company said that BCHT held a complementary licence to the LAIV for the public market in China via a sublicence from the World Health Organisation (BD: Aug 1, 2011).

Biodiem said that BCHT was a well-established technology company engaged in medical research and development, marketing and production in Jilin Province's High Tech Zone.

Biodiem said that BCHT was established in 2004, had more than 600 employees and developed significant in-house expertise in viral technology development with particular successes in the areas of influenza and preventative HIV vaccines.

Biodiem said that its vaccine could be delivered by a nasal spray, eliminating the need for injections, increasing patient acceptability and compliance and it produced a broader immune response, more akin to the natural immune response, than standard flu injections.

In a media release to the ASX, Ms Phillips said the company was "delighted to have secured another licence for our LAIV technology".

"BCHT is an experienced and well-regarded vaccine developer and producer," Ms Phillips said.

Ms Phillips said that BCHT had its own research and development and production facilities and marketed products.

BCHT president Dr Wei Kong said his company saw "a huge opportunity in building a LAIV influenza vaccine platform in China".

"The LAIV technology's versatility and ability to be administered without injection makes it a very attractive asset, which we believe will be particularly competitive in China," Dr Kong said.

Biodiem said the licencing deal would "substantially expand the application of LAIV technology and promote [its] business prospects".

Biodiem was untraded at 7.5 cents.

## PATRYS

Patrys says that patient treatment has been completed in its phase I trial of PAT-SM6 for melanoma.

Patrys said the primary trial objective was to establish safety and tolerability and no significant safety issues were observed or reported for any patients treated with PAT-SM6.

The company said that the secondary trial objective was to measure the anti-tumor activity of PAT-SM6 and the full trial data is expected to be available by the end of March, 2012.

In August 2011, Patrys reported that analysis of tumor samples from two patients treated with PAT-SM6 found that the antibody had penetrated into the tumor, even though the doses were substantially below the anticipated therapeutic levels (BD: Aug 22, 2011).

Patrys chief executive officer Dr Marie Roskrow said the company looked forward to reporting detailed data and "the fact that we have hit the primary endpoint of the trial is very encouraging".

"We are now able to move forward confidently with planning of our next PAT-SM6 clinical trial for patients with the blood cancer, multiple myeloma," Dr Roskrow said.

Patrys fell 0.1 cents or 2.5 percent to 3.9 cents.

## SUNSHINE HEART

Sunshine Heart says it has agreements with US and Australian investors to raise $2.1 million through the placement of 257,000 shares of common stock to list on Nasdaq.
Sunshine Heart said the common stock was equivalent to about 51.4 million Chess Depositary Instruments (CDIs).
The company said the funds were for its listing on the Nasdaq exchange.
Sunshine Heart said the placement was at the same price as the September 2011 placement at four cents per Australian share or $8.00 per US share.
The company said that the investors would receive warrants to purchase three shares of common stock for every 10 shares purchased, at an exercise price of $A11.20 per share or 5.6 cents per CDI, with a four year term.
Sunshine Heart said that Summer Street Research Partners was the placement agent for the transaction in the US, and RBS Morgans assisted with the placement in Australia.
Sunshine Heart chief executive officer Dave Rosa said that the Nasdaq listing was “an important milestone for the company as we prepare for US market entry”.
Sunshine Heart was untraded at 3.6 cents.

## IMPEDIMED

Impedimed says it expects to increase its US reimbursement coverage for its L-Dex device for lymphoedema by about 700,000 people.
Impedimed said the US Patient Protection and Affordable Care Act (Obamacare) made certain indigenous tribes and organizations eligible to access the health plans for Federal employees and the company expected an increase in covered lives for Federal healthcare plans from May 1, 2012.
Impedimed said the first patient had been enroled in the Stanford Breast Cancer Lymphoedema Registry, which will collect and analyse data from breast centres and physicians offices across the US (BD: Dec 13, 2012).
The company said the data collected would be mined by the investigators in order to gain insight into the natural history and optimal management of lymphoedema.
Impedimed fell 2.5 cents or 4.7 percent to 50.5 cents.

## BPH ENERGY, CORTICAL DYNAMICS

BPH investee company Cortical Dynamics has been approved for a Western Australian Department of Commerce Innovation Vouchers Program.
BPH said that the program was designed to give financial assistance to engage professional skills or services that help innovative products become a commercial reality.
The company said the funds would be used to assist Cortical obtain regulatory approval for the brain anaesthesia response (BAR) monitor, which measures a patient’s brain electrical activity via an electroencephalogram to indicate how deeply anaesthetised a patient is during an operation.
BPH and Cortical chairman David Breeze, said that Cortical would require regulatory approval before it can begin selling the BAR monitor and a consultant wouldill provide the expert support and assistance to help the company meet regulatory approval requirements.
BPH fell 0.1 cents or 3.7 percent to 2.6 cents.

## IMMURON

Immuron says it has been the subject of “misinformation regarding the terms of the convertible debenture agreement … with Paladin Labs (BD: Jan 22, 2012).
Immuron did not disclose the source of the alleged misinformation.
In January, Immuron said the agreement with Canada’s Paladin Labs facilitated up to $C1.5 million, following the Travelan for diarrhea distribution licence agreement (BD: Nov 29, 2011).
The company said the initial drawdown would be $C100,000 and included a coupon rate of 10 percent not due for repayment for three years and Paladin had the right to convert all or part of the funds into shares of at an agreed conversion price of 4.73 cents a share.
Today the company said the “misinformation related to the assets of the company that are encumbered under the debenture and could have been interpreted to, erroneously, include Immuron’s intellectual property”.
“Immuron’s intellectual property is not encumbered under the debenture in any way,” Immuron said in a media release to the ASX.
Immuron said it was “vigilant to ensure that its ability to continue to commercialize all of its products and intellectual property remains absolutely unfettered” and the assets encumbered were its bank accounts, receivables, inventories and future payments, including milestones and royalties.
Immuron said “this principle was vital in [the] board unanimously approving the Paladin transaction on November 28, 2011”.
Immuron said the terms of the November 2011 Paladin agreement a $C500,000 upfront licence fee, milestone payments over the 15 year term of the agreement with the potential to amount to $C115 million and Immuron retaining all Travelan intellectual property rights and manufacturing.
The company said that Paladin was in the process of seeking regulatory approvals for the distribution of Travelan in the territories covered by the agreement and expected its activities would contribute to Immuron’s revenues as early as this year.
Immuron fell 0.1 cents or 2.8 percent to 3.5 cents with 1.5 million shares traded.

## VIRALYTICS

Viralytics says that having converted the final balance of the $US6 million convertible note into shares, La Jolla Cove Investors have disposed of their entire Viralytics holding.
Viralytics said that the La Jolla Cove facility “provided valuable funding for Viralytics over the last three years, leading up to the commencement of our important phase II US clinical trial”.
The company said that it was “in a strong position to fund its ongoing research and development plans with $7.7 million cash in hand and no debt”.
Viralytics was unchanged at 36.5 cents.

## BONE MEDICAL

La Jolla Cove Investors has become a substantial shareholder in Bone with the acquisition of 17,500,000 shares or 10.5 percent of the company.
La Jolla Cove said it paid $115,000 for the holding or 0.66 cents a share.
Bone fell 0.2 cents or 11.8 percent to 1.5 cents with 1.6 million shares traded.

## AVITA MEDICAL

Avita says it has passed audits of its quality management system, medical devices certification and Canadian medical devices regulation.

Avita said that recertification audits of the required elements were conducted once every three years and its audit was conducted in November of 2011 by an independent, external auditor of the European notified body.

The company said the audit addressed all phases of its quality, manufacturing and management systems and verified the controls on its portfolio of medical products including the wound treatment and regenerative product, Recell Spray-On Skin, as well as the company's respiratory products Funhaler and Breath-A-Tech.

Avita said that successful recertification was a requirement to maintain its Conformité Européenne (CE) mark on its products for sale within the European Union and Canada as well as a reference for registration in other countries.

Avita fell half a cent or 3.7 percent to 13 cents.

## OBJ

OBJ has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose from 1.8 cents on February 2, 2012 to 2.3 cents on February 8, 2012, a 27.8 percent increase and noted an increase in trading volume.

OBJ fell 0.1 cents or 4.55 percent to 2.1 cents with 7.6 million shares traded.