

# Biotech Daily

Wednesday August 15, 2012

Daily news on ASX-listed biotechnology companies

- \* ASX UP, BIOTECH DOWN: CLINUVEL UP 10%, IMPEDIMED DOWN 13%
- \* REVA STENT TRIAL: NO ADVERSE EVENTS; PIVOTAL TRIAL PLANNING
- \* IMMURON TESTS IMM-255 AGAINST SWINE 'FLU IN FERRETS
- \* BIONOMICS REVENUE UP 68% TO \$7m, LOSS DOWN 67% TO \$3m
- \* 'KEY US PATENT' FOR BIONOMICS BNC105
- \* UP TO 17% OF EGM VOTES OPPOSE PATRYS DIRECTOR SHARES

#### MARKET REPORT

The Australian stock market fell 0.26 percent on Wednesday August 15, 2012 with the S&P ASX 200 down 11.0 points to 4,281.2 points.

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

Clinuvel was the best, up 15 cents or 10 percent to \$1.65 with 28,644 shares traded.

Mesoblast climbed 7.7 percent; Antisense was up 6.25 percent; Allied Health and Patrys were up more than five percent; Prana was up 3.2 percent; QRX rose 2.9 percent; Acrux and Circadian were up more than one percent; with Cochlear, CSL, Pharmaxis and Starpharma up by less than one percent.

Impedimed led the falls, down 2.5 cents or 13.2 percent to 16.5 cents with 168,000 shares traded, followed by Cellmid down 11.1 percent to 1.6 cents with 2.3 million shares traded.

Phylogica lost 7.4 percent; Neuren and Prima fell more than four percent; Alchemia, Avita, Phosphagenics and Universal Biosensors were down more than three percent; Sunshine Heart shed 2.8 percent; Anteo and Bionomics were down more than one percent; with Psivida down 0.6 percent.

# **REVA MEDICAL**

Reva chief executive officer Bob Stockman told an investor teleconference that all 26 patients in its pilot trial of the Rezolve cardiac stent were free of adverse events, to date. Mr Stockman said that, to date, the first patient had reached the eight months point since the implant of the drugeluting bio-resorbable stent and there had been no major adverse cardiac events.

Mr Stockman said the patients would be followed for five years.

Mr Stockman said the pilot trial, known as the 'Restore' trial would have a second arm trialing the company's Rezolve2 stent.

Mr Stockman told Biotech Daily that the precise number of patients had not been established but would be "close to the completion of the original 50 patient trial", implying about 20 to 30 patients.

He said that the Rezolve2 stent was 30 percent stronger than the original model and had been refined so that it did not need the cover sheath, making the device thinner and easier for insertion.

Mr Stockman said that preparations were underway for a pivotal Conformité Européenne (CE) mark trial of up to 150 patients in Brazil, Europe, Australia and New Zealand. Mr Stockman said he hoped to begin the trial by April 2013 with results and CE mark approval in mid-2014.

Reva was unchanged at 55 cents.

### **IMMURON**

Immuron says that its IMM-255 influenza candidate is being tested in ferrets against the A/California/7/2009 influenza strain, once referred to as 'Swine 'Flu'.

Immuron said the ferret studies should provide results by the end of 2012 and were designed to demonstrate the ability of the cow colostrum-derived IMM-255 to prevent influenza in addition to supporting its applicability claim to current strains of influenza. The company said that IMM-255 was being developed as a dual-acting over-the-counter consumer product enriched with anti-influenza antibodies for both mucosal protection against influenza viruses and the boosting of the immune system to fight infection. Immuron said that it expected IMM-255 to have a high safety profile similar to its Travelan drug for travelers' diarrhoea.

The company said that previous studies, using the Solomon Islands H1N1 strain, had shown a positive signal, demonstrating a temporary interference in virus production in the animals treated with the Immuron antibody preparation.

Immuron said it had previously demonstrated that IMM-255 was effective in both treating and preventing infection of the PR-8 strain influenza in a mouse model when delivered nasally.

Immuron chief executive officer Joe Baini said the additional studies would provide "further confidence in delivering this novel Influenza product effectively".

"Immuron is therefore continuing with the development program to confirm these predictions," Mr Baini said.

"We are making material progress in demonstrating the applicability of the Immuron technology in preventing and treating influenza, which will further strengthen our commercial prospects in the global influenza markets," Mr Baini said.

Immuron said that the current direct medical costs in the US alone related to influenza were more than \$US10 billion.

Immuron was unchanged at 1.8 cents.

# **BIONOMICS**

Bionomics says it net loss after tax for the 12 months to June 30, 2012 was down 66.5 percent to \$3,136,238 on revenue up 67.9 percent to \$6,834,709.

Bionomics said the revenue consisted of research and development payments under agreements, primarily with Ironwood for anti-anxiety drug BNC210, as well as the Merck Serono agreement, along with royalties on licenced epilepsy diagnostic tests, contract service revenue from its wholly-owned European subsidiary Neurofit SAS, rental income and interest income received as a result of our ordinary activities.

The company said that government grants and assistance were separately classified under other income.

Bionomics said diluted loss per share fell 69.0 percent from 2.9 cents in the previous year to 0.9 cents for the year to June 30, 2012.

The company said it had cash and cash equivalents of \$17,336,609 at June 30, 2012 up 8.0 percent on the previous year.

Bionomics said that net tangible assets per share was down 12.3 percent to 5.0 cents. Bionomics fell half a cent or two percent to 25 cents.

# **BIONOMICS**

Bionomics says the US Patent and Trademark Office has granted its "key patent" relating to its vascular disrupting agent BNC105.

Bionomics said that US patent number 8,198,466 entitled' Substituted benzofurans, benzothiophenes, benzoselenophenes and indoles and their use as tubulin polymerisation inhibitors' was "at the centre of the BNC105 patent portfolio" and was valid to February 2027.

The USPTO abstract said the invention "relates generally to substituted benzofurans, benzothiophenes, and indoles and their use as tubulin polymerization inhibitors". Bionomics said that BNC105 patents had been filed in each of the major pharmaceutical markets and this patent had been filed in Australia and New Zealand.

The company said that BNC105 recently entered a phase I/II trial in combination with carboplatin and gemcitabine for ovarian cancer in Australia, New Zealand and the US following preclinical data showing synergy with platinum-based agents (BD: May 24, 2012).

Bionomics said BNC105 was also undergoing evaluation in a phase II US multi-centre trial in combination with mTOR inhibitor (Afinitor) in metastatic renal cell carcinoma, a form of kidney cancer. (BD: Aug 3, Sep 20, 2011).

Bionomics chief executive officer Dr Deborah Rathjen said the granting of the patent in the US was "a milestone in Bionomics' patent strategy for the BNC105 program".

"This solidifies our intellectual property protection for Bionomics' lead oncology clinical stage asset," Dr Rathjen said.

"The granted patent provides a substantial value-add for the BNC105 program and strengthens our partnering data package," Dr Rathjen.

Bionomics said it had filed a patent application for the manufacture of BNC105 and owned additional patents and had applications covering vascular disrupting agents related to BNC105, together with methods of treatment of cancer both as monotherapy and in combination with selected therapies.

# **PATRYS**

Patrys shareholders have passed all five extraordinary general meeting resolutions with some dissent against all resolutions (BD: Jul 16, 2012).

All resolutions related to the recent placement at two cents a share and all were opposed by about 10.5 million proxy votes (7.5%), with four resolutions supported by more that 129 million votes (92.5%).

The resolution to issue 2,500,000 shares to director Michael Stork's Stork Holdings was passed with 50,651,396 proxy votes (82.75%) in favor and 10,558,364 proxy votes (17.25%) against.

The votes opposing the resolutions amounted to 2.55 percent of the 413,612,177 shares on issue.

Patrys was up 0.1 cents or 5.3 percent to two cents.