



# Biotech Daily

Tuesday June 11, 2013

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH UP: COMPUMEDICS UP 24%, TISSUE THERAPIES DOWN 7%**
- \* **QBIOTICS RAISING \$10m FOR RAINFOREST CANCER, WOUND DRUG**
- \* **INVION PLACEMENT RAISES \$2m**
- \* **PATRY'S PAT-SM6 FOR MELANOMA DATA PUBLISHED**
- \* **COMPUMEDICS \$500k FUNDING**
- \* **SINGAPORE GRANTS NUSEP PLASMA IMPORT LICENCE**
- \* **BIONOMICS COMPLETES PHASE II BNC105 KIDNEY ENROLMENT**
- \* **71% OF DOCTORS IN ISONEA SURVEY BACK AIRSONEA**

## MARKET REPORT

The Australian stock market was up 0.41 percent on Tuesday June 11, 2013 with the S&P ASX 200 up 19.4 points to 4,757.1 points. Seventeen of the Biotech Daily Top 40 stocks were up, 10 fell, nine traded unchanged and four were untraded. All three Big Caps rose.

Compumedics was the best, up 1.2 cents or 23.5 percent to 6.3 cents, with 30,000 shares traded, followed by Allied Health up 13.6 percent to five cents, with 23.5 million shares traded, in the wake of an interview with 44 percent subsidiary Coridon founder Prof Ian Frazer relating to the company on the weekend, and Circadian up 11.1 percent to 30 cents with 4,450 shares traded.

Antisense climbed 9.1 percent to 1.2 cents with 11.4 million shares traded, Neuren was up 6.7 percent; Anteo, Nanosonics and Sirtex were up more than five percent; Psivida and Viralytics climbed more than four percent; Genetic Technologies, Mesoblast and Patrys were up more than three percent, Cochlear, Prana and Starpharma rose more than two percent; CSL, Resmed and Universal Biosensors were up more than one percent; with Acrux up 0.3 percent.

Tissue Therapies led the falls, down one cent or 6.7 percent to 14 cents, with 115,966 shares traded.

Clinuvel lost 5.9 percent; Living Cell fell 4.3 percent; Bionomics and Cellmid were down more than three percent; Alchemia and GI Dynamics shed more than two percent; with Heartware, Medical Developments and QRX down by less than one percent.

## QBIOTICS

QBiotics says it has commitments for \$8 million of \$10 million it hopes to raise for a human cancer trials and progress a potential new wound healing product.

In 2011, Queensland's Ecobiotics said it would fund University of Queensland scientist Dr Craig Williams for three years to develop medical therapies from ancient rainforest species (BD: Feb 11, 2011).

The University of Queensland's commercialization arm Uniquist said at that time that it had facilitated the \$10 million contract extension and Dr Williams had been working with Ecobiotics for six years researching the discovery and development of new chemicals from rainforest plants for use in pharmaceuticals and food additives for humans and animals, including anticancer compound EBC-46 for solid tumors in humans and animals. Today, the Yungaburra-based QBiotics said EBC-46 came from the North Queensland's rainforest blushwood and "demonstrated remarkable anti-tumor properties in clinical treatment of cancer in companion animals".

QBiotics said it was raising \$10 million to fund human anti-cancer trials with this drug and to implement a research program to further evaluate the wound healing potential of a new compound derived from the same plant called WH-1.

QBiotics chief executive officer Dr Victoria Gordon said that EBC-46 had proven efficacy with a wide range of animal tumors, "but the company's work in wound healing has now opened up a whole new range of possibilities".

"Some of the wound healing we've witnessed so far in pilot studies with pet dogs has been remarkable," Dr Gordon said. "These animals had chronic non-healing wounds that weren't responding to current standard-of-care treatments before being treated with our new compound," Dr Gordon said.

Dr Gordon said that wound healing was worth \$US14 billion a year in the US alone and his company would evaluate developing the drug for both chronic and acute wounds.

"Both our anticancer and our wound healing products are very different types of drugs to those currently available for treating these indications," Dr Gordon said.

"Essentially, they let the patient's body do the work," Dr Gordon said.

"They act as signaling molecules which turn on the body's own immune system to attack the tumor or accelerate the natural wound healing process," she said. "These drugs also have the advantage of being easy to administer and cause minimal trauma."

QBiotics said the research programs would be run in Australia and the capital raising was managed by corporate finance manager Reuben Buchanan.

QBiotics said it would issue a prospectus for the capital raising, but would remain an unlisted public company, for the time being.

The prospectus is at: [www.qbiotics.com/invest](http://www.qbiotics.com/invest).

## INVION (FORMERLY CBIO)

Invion says it has raised \$2,025,100 through the issue of 53,292,115 shares at 3.8 cents a share in a placement to new and existing investors in Australia, the US and Europe.

Invion said the funds were for the development of INV102 (nadolol) and INV103, formerly known as XToll of chaperonin 10, and general working capital.

Invion chief executive officer Dr Greg Collier said the placement "demonstrates strong interest from professional investors to see the advancement of Invion's programs" and along with a recent share purchase plan, the company had raised more than \$3.1 million (BD: May 17, 2013).

The company said that RBS Morgans was the lead manager for the placement.

Invion fell 0.6 cents or 15.8 percent to 3.2 cents.

## PATRYS

Patrys says its preclinical and clinical data supporting PAT-SM6 for melanoma has been published in the journal Melanoma Research.

Patrys said the article, entitled 'Early development of PAT-SM6 for the treatment of melanoma', was co-written by research and development vice-president Dr Frank Hensel, was available online and would be in the August 2013 print edition of the journal.

A summary of the article is available at: <http://www.ncbi.nlm.nih.gov/pubmed/23728394>.

Patrys said the article provided a summary of the results of preclinical studies conducted in melanoma which confirmed that PAT-SM6 induced programmed tumor cell death by interacting with a specific isoform of glucose-regulated protein 78 (GRP78) present on the surface of malignant cells but not normal cells.

The company said that the results showed that the interaction of PAT-SM6 with low density lipoprotein was responsible for the accumulation of lipids in melanoma cells and even more effective cell death.

Patrys said that in-vitro cell data was supported by positive in-vivo animal data evaluating PAT-SM6 in an aggressive and metastatic mouse model where animals injected with melanoma tumor cells would develop metastases, or secondary tumors, in their lungs.

The company said that treatment with PAT-SM6 significantly suppressed or eliminated the development of these secondary tumors in all treated mice.

Patrys said that PAT-SM6 was safe and well-tolerated in cynomolgus (macaque) monkey toxicology studies and the publication included an overview of the phase I melanoma clinical trial completed in February 2012.

The company said that the trial met its primary endpoint of safety and showed early evidence supporting the ability of PAT-SM6 to specifically target melanoma tumors and cause cell death (BD: Mar 20, 2012).

The article concluded that the PAT-SM6 recombinant human monoclonal antibody "specifically and selectively binds cell surface-expressed GRP78 and is capable of killing melanoma cells".

"It has shown efficacy in a mouse animal model and is safe in monkeys," the article concluded. "It was well tolerated in patients with recurrent in-transit melanoma at the dose range of 0.15–0.60 mg/kg [and] no patients developed antibodies against PAT-SM6."

The journal article said that "pharmacokinetic analysis indicated dose-proportional increases ... quick clearance and a short half-life, providing future dosing guidance".

"These findings justify the move forward to larger multi-dose trials in patients with melanoma and other PAT-SM6-expressing tumors," the article concluded.

Patrys was up 0.1 cents or 3.3 percent to 3.1 cents with 2.1 million shares traded.

## COMPUMEDICS

Compumedics says it has received the first \$400,000 of a \$2.5 million working capital facility with Bibby Financial Services (BD: Jun 3, 2013).

Compumedics said it had also secured a \$100,000 loan from its US-based director, Alan Anderson.

Last week, Compumedics said the funding would enable it to ship "a record \$10 million of sales orders" and it expected to return to profitability by September 2013.

The company said it had secured a further long-term electroencephalogram (EEG) monitoring (LTEM) site in the US, confirming previous announcements that its new neurology monitoring line would strengthen growth prospects.

Compumedics was up 1.2 cents or 23.5 percent to 6.3 cents.

## NUSEP

Nusep says that Singapore has granted 90 percent subsidiary Prime Biologics an importation licence for human plasma.

Nusep said that the licence would allow Prime to import human plasma from other countries, such as India, for processing and re-export as finished therapeutic plasma products.

The company said the licence was required as part of its clinical good manufacturing practice application, which it expected to lodge within the next six months.

Nusep was untraded at 6.3 cents.

## BIONOMICS

Bionomics says it has completed enrolment of 135 patients in its phase II trial of BNC105 with everolimus (Afinitor) for advanced renal cell carcinoma.

Bionomics said it was the first and only randomized trial to test the combination of a mammalian target of rapamycin (mTOR) inhibitor (Afinitor) with a vascular disrupting agent, BNC105, in renal cancer.

Bionomics chief executive officer Dr Deborah Rathjen said the completion of enrolment was "an important achievement for Bionomics".

"It is particularly exciting to reach this milestone in a trial which has the potential to create a new paradigm for the treatment of renal cancer," Dr Rathjen said.

"We have always said that we would be looking to partner this program once we had sufficient data from our clinical trials and achieving this milestone is an important step in the path to partnership," Dr Rathjen said.

Bionomics chief medical officer Dr José Iglesias said that BNC105's mechanism of action provided "an innovative approach to the treatment of solid tumors, including metastatic renal cell carcinoma, by attacking established tumor vasculature".

"We believe that there is a strong scientific rationale for this combination, as well as compelling preclinical and phase I data that support this approach," Dr Iglesias said.

"Afinitor and BNC105 work by different but complementary mechanisms of action," Dr Iglesias said.

"The vascular disrupting effect of BNC105 causes hypoxic stress and Afinitor concurrently blocks the mTOR driven recovery pathway of renal tumors," he said.

"Treatment options remain limited in progressive metastatic renal cell cancer for patients who have failed tyrosine kinase inhibitor therapy and BNC105 has the potential to broaden treatment options for these patients," Dr Iglesias said.

Bionomics said that the phase II trial was conducted at sites across the US, Australia and Singapore and enrolled 135 patients with advanced metastatic renal cell carcinoma, who had failed prior therapy with tyrosine kinase inhibitors such as Sutent and were randomized into either receiving Afinitor or Afinitor with BNC105.

The company said that patients were treated until disease progression or until adverse effects prohibited further therapy.

Bionomics said that renal cell carcinoma accounted for about 85 percent of kidney cancers, with about 200,000 cases diagnosed worldwide and 55,000 people diagnosed each year, in the US alone and the five year survival rate for patients with metastatic disease was less than two percent.

Bionomics said that the cost of treating the disease was also significant with the market for drugs targeting renal cell carcinoma estimated at \$US2.5 billion a year and in 2012, Afinitor had sales worth \$US700 million.

Bionomics fell 1.5 cents or 3.9 percent to 37 cents.

## ISONEA

Isona says a survey of 100 doctors supported its Airsona technology to be launched in Australia in September 2013.

Isona said the study was conducted by independent US-based research specialists Dectiva and focused on 100 Australian physicians involved in asthma treatment and included 50 paediatricians.

The company said that 80 percent of general practitioners and 62 percent of pediatricians in the study would recommend the mobile monitoring system, which enabled wheeze rate monitoring via smart-phone, to all asthma patients.

Isona said that additional scientific data on the technology would increase recommendations and the doctors regarded a mobile wheeze monitoring device as suitable for 75 percent of unstable asthma patients who required daily monitoring.

Isona chief executive officer Michael Thomas said the findings provided further critical support for the company's innovative acoustic monitoring technology.

"This device will change the way millions of asthma sufferers around the world manage and monitor their conditions," Mr Thomas said.

"Data from this latest study demonstrates that medical professionals are supportive of our endeavor and plan to recommend it to appropriate patients for daily monitoring and management of their asthma," Mr Thomas said.

The company said that the study found that most physicians diagnosed asthma from patient medical history and auscultation or listening to breath sounds with a stethoscope, so the approach of monitoring breathing sounds with a device is consistent with clinical practice and the presence of wheeze was significantly higher in patients with unstable asthma, which accounted for 60 percent or more of asthma patients.

Isona said the doctors surveyed considered home monitoring of asthma "very important", to assist managing patient asthma action plans and to ensure medication adherence and said that, historically, asthma had been monitored by peak flow meters or diaries, but these systems suffered from low compliance and poor reliability.

The company said that paediatricians specifically were concerned about low compliance with peak flow usage in younger patients.

"Most physicians indicate that asthma monitoring data is only reviewed during office visits with approximately half of their patients," Mr Thomas said.

Mr Thomas said that general practitioners and pediatricians indicated that the availability of more real time data on symptoms, asthma events and breathing sounds would be valuable for their patient management.

Isona was unchanged at 35 cents with 2.5 million shares traded.