Biotech Daily

Tuesday September 20, 2011

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ANTISENSE UP 25%; PRANA DOWN 14%**

*** SPINIFEX STARTS PHASE II EMA401 POST-HERPETIC NEURALGIA TRIAL**

*** ADVANCED SURGICAL TO DISTRIBUTE SPINAL IMPLANTS**

*** ANTISENSE APPLIES FOR ATL1102 STEM CELL MOBILIZATION PATENT**

*** BENITEC EXPEDITES DD-RNA-I PAIN PROGRAM**

*** BIONOMICS INCREASES BNC105 DOSE FOR KIDNEY CANCER**

*** NOVOGEN, MARSHALL EDWARDS TREAT 1st SOLID TUMOR PATIENT**

*** INJECTION SITE REACTIONS CLOSE PROGEN PG545 TRIAL**

*** PATRYS PAT-SM6 MOUSE DATA SHOWS OVARIAN CANCER POTENTIAL**

*** ORBIS TAKES 9% OF QRX**

*** TOM ROWE REPLACES JENNIE YUEN AS VIRALYTICS CO SEC**

MARKET REPORT

The Australian stock market fell 1.01 percent on Tuesday September 20, 2011 with the S&P ASX200 down 41.3 points to 4,040.2 points. Seven of the Biotech Daily Top 40 stocks were up, 18 fell, eight traded unchanged and seven were untraded.

Antisense was best, up 0.2 cents or 25 percent to one cent with 52.9 million shares traded, followed by LBT up 17.4 percent to 5.4 cents with 144,081 shares traded. Patrys climbed 6.8 percent; Benitec was up 4.55 percent; CSL and Tissue Therapies rose more than two percent; with Mesoblast up one percent; and Pharmaxis up 0.6 percent.

Prana led the falls, down three cents or 14.3 percent to 18 cents with 937,317 shares traded, followed by Living Cell down 10.3 percent to 5.2 cents with 427,100 shares traded and Optiscan down 10 percent to nine cents with 269,750 shares traded.

Allied Health fell 7.7 percent; Acrux and Compumedics lost more than six percent; Alchemia was down 5.4 percent; Clinuvel, Universal Biosensors and Viralytics fell four percent or more; Cochlear was down 3.8 percent; Circadian, Genetic Technologies, Prima, Reva and Sunshine Heart shed more than two percent; with Sirtex and Starpharma down more than one percent.

SPINIFEX PHARMACEUTICALS

Spinifex says the first patients have been treated in its 170-patient phase II clinical trial of EMA401 in post-herpetic neuralgia.

Spinifex said post-herpetic neuralgia was a painful condition in some patients following herpes zoster, or shingles, and existing therapy did not relieve pain in all individuals.

The company said the double-blind, placebo-controlled, randomized trial was being conducted at centers in five countries and the first patient was treated at the Pretoria, South Africa clinic of Dr Douwe De Jong.

Spinifex said the trial was designed to prove the concept of the use of EMA401, an angiotensin II type 2 (AT2) receptor antagonist, in post-herpetic neuralgia and determine its safety, tolerability and pharmacokinetic profile.

The company said the primary endpoint of the trial was the reduction in mean daily pain score versus placebo over the last week of 28 days of treatment.

Spinifex said secondary endpoints included further measures of pain and quality of life.

Spinifex chief executive officer Dr Tom McCarthy said the dosing was “an important new step in the development of EMA401 and of Spinifex”.

“We have successfully applied our development expertise to take a scientific discovery through early clinical development and now into proof-of-concept trials,” Dr McCarthy said.

“This is the first of three phase II trials to be initiated and we look forward to confirming the promise for EMA401 we have seen in our earlier clinical and pre-clinical studies.”

The trials principal investigator at the Christiaan Barnard Memorial Hospital in Cape Town Dr Milton Raff said that current treatments for post-herpetic neuralgia were effective in some patients “but a significant proportion either don’t respond to therapy and are left with debilitating symptoms or suffer significant side effects”.

“EMA401 offers an entirely novel approach to the treatment of the condition and could represent a valuable new option in an area where there is a clear need for new medicines,” Dr Raff said.

Spinifex said the EMA401 clinical program would include studies in other neuropathic pain indications including pain and hypersensitivity in peripheral nerve injury patients and pain and hypersensitivity in cancer chemotherapy patients.

The company said the market for neuropathic pain treatments was expected to continue to increase and was projected to reach $US6.2 billion by 2017.

Spinifex is a private company.

ADVANCED SURGICAL DESIGN AND MANUFACTURE

Advanced Surgical says it will distribute products for the Texas based Orthofix Spinal Implants an indirect subsidiary of the Netherlands-based Orthofix International NV.

Advanced Surgical said it would be the exclusive Australian distributor for the full range of Orthofix’s spinal products.

Advanced Surgical chief executive officer Dr Greg Roger said the Orthofix Spine range opened up additional sales opportunities.

“Importantly, Orthofix has a first class product and an established user base of Australian surgeons and has invested significantly in the past two years to create the next generation of spinal products,” Dr Roger said.

Dr Roger said the products were ready to be released in Australia “early in 2012”.

“Our clear strategy is to rapidly and profitably grow our business by offering a comprehensive product range and outstanding service to a growing population of orthopaedic surgeons,” Dr Roger said.

Advanced Surgical was untraded at 15 cents.

ANTISENSE THERAPEUTICS

Antisense says its multiple sclerosis drug ATL1102 shows potential as a stem cell mobilization agent in stem cell transplantation.

Antisense said data from previous ATL1102 studies formed the basis of an international patent application entitled 'Method of mobilizing stem cell and/or progenitor cells'.

The company said the application sought protection for the stem cell mobilization application of ATL1102 until 2031 and if granted, would add to the intellectual property position established on ATL1102 to underpin its commercialization.

Antisense said that stem cell transplantation was a procedure to improve clinical outcomes for patients undergoing chemotherapy to treat cancer.

The company said that haematopoietic stem cells were parent cells to blood and immune cells produced in bone marrow and to overcome chemotherapy toxic effects on bone marrow, they were collected from the patient's or a donor's blood before chemotherapy to replace those lost during chemotherapy.

Antisense said stem cell mobilization agents were typically used to increase the number of haematopoietic stem cells before stem cell collection.

Antisense said that granulocyte colony stimulating factor (G-CSF) was the main agent used for haematopoietic stem cell mobilization and the market for G-CSF agents was several billion dollars a year.

The company said that G-CSF was successful in mobilizing haematopoietic stem cells, but there was an opportunity to improve on the level of stem cell release with G-CSF alone by the addition of complimentary therapies, the role envisaged for ATL1102.

Antisense said one complimentary therapy, Mozobil had been approved for use in combination with G-CSF, with about $100 million in sales in 2010.

The company said Mozobil had orphan drug status in the US and European Union for the mobilization of haematopoietic stem cells and while Mozobil boosted the number of stem cells released beyond G-CSF alone, a need remained for agents that could improve on the level of stem cell release achieved with the G-CSF and Mozobil combination.

Antisense said ATL1102 had a novel action different to both G-CSF and Mozobil in targeting the VLA-4 receptor, the blocking of which had been shown to aid in the release of stem cells from the bone marrow and ATL1102 could be used in place of Mozobil if it demonstrated superiority, or with both G-CSF and Mozobil to enhance their effects.

The company said that a version of ATL1102 designed to work in mice was used over seven, 10 and 14 days in combination with G-CSF given on the last three days of treatment, releasing one of the recognized stem cells up to 13 times more ($p < 0.01$) compared to saline control at day 14, and seven times more than with G-CSF used alone ($p = 0.05$).

Antisense said the animal data supported a relatively quick pharmacological action of the drug, with stem cell increases being achieved within a week of treatment, as well as the drug's potential to be used in combination with G-CSF to increase the level of stem cell mobilization beyond G-CSF alone.

The company said a phase II study of ATL1102 in relapsing-remitting multiple sclerosis patients, ATL1102 increased CD34 RNA 1.5 times ($p < 0.027$) at eight weeks compared to baseline in total blood RNA of the patients, demonstrating activity in humans.

Antisense said ATL1102's safety profile in stem cell mobilization was supported by the phase II trial in multiple sclerosis patients, where the drug was administered for eight weeks and was viewed as safe and well tolerated.

The company said it continued to seek a new partner to further develop ATL1102 for multiple sclerosis.

Antisense was up 0.2 cents or 25 percent to one cent with 52.9 million shares traded.

BENITEC

Benitec says it is expediting pre-clinical, clinical and commercial development of its lead program, a gene-silencing therapeutic for intractable cancer-associated neuropathic pain.

Benitec said the North Carolina-based consulting firm Campbell Alliance Group had completed the first stage of a commercial evaluation engagement, with encouraging results.

The company said that Campbell Alliance assessed the market potential of its DNA-directed RNA interference (ddRNAi) product in the cancer-associated pain market, estimated at being worth $3.1 billion in the US in 2009.

Benitec said pain specialists rated the attractiveness of the potential Benitec product highly due to its mechanism of action and potential for minimal toxicity.

The company said the potential for the product to treat neuropathic pain was seen by key opinion leaders as beneficial, as it might avoid the side effects and other limitations of opioids and other treatments.

Benitec said the Campbell Alliance report estimated the revenue potential of the product for terminal cancer pain patients in palliative care alone to be about $600 million a year.

The company quoted the report saying that indications beyond cancer pain, including shingles and diabetic neuropathy, could also be targeted, increasing its potential use and potential revenue.

Benitec chief executive officer Dr Peter French said the report's findings "validate our pain program directly from the pain clinicians themselves".

"It reinforces our focus on the pain program and provide the impetus for Benitec to mobilize additional resources to the program and to progress to the next stage of Benitec's commercial outreach for this program in the US and Europe with Campbell Alliance," Dr French said.

Benitec said it had appointed the US-based Ground Zero Pharmaceuticals as the contract research organization to advance the pain program into clinical testing under a US Food and Drug Administration-approved protocol and had appointed Mariam Ajaj as its regulatory compliance officer to work with Ground Zero.

The company said it had contracted the University of Queensland-based Tetraq for the pre-clinical testing required for the regulatory process.

Benitec said that founding scientist Dr Mick Graham was supervising this part of the project, as a consultant.

Dr French said that the pain program was at an early preclinical stage, but "we are aware of the significant unmet clinical need for a product with the unique features of our technology, and therefore we are seeking to fast track its development".

"I believe this is a unique opportunity for Benitec to demonstrate the power and potential of our gene silencing technology in both clinical and commercial settings over the next 12 months," Dr French said.

Benitec said Dr French would present a poster entitled 'A New Class of Pain Therapeutics – ddRNAi Gene Constructs' co-authored with Dr Graham on the gene silencing approach for neuropathic pain at the Pain Therapeutics Summit in San Francisco on September 21, 2011.

The poster said that the target was protein kinase C gamma and concluded that the studies to date indicated "that ddRNAi, used to produce a long-term knockdown of gene expression in the spinal cord, can act as a new class of pain therapeutic molecules, with a unique mechanism of action and potential for minimal toxicity".

Benitec was up 0.1 cents or 4.55 percent to 2.3 cents with 19.2 million shares traded.

BIONOMICS

Bionomics says it has increased the dose of vascular disrupting agent BNC105 in its US phase II clinical trial of BNC105 with Afinitor in patients with metastatic renal cell cancer.
Bionomics said it had previously cleared a dose of 12.6mg/m2 and it had evaluated the higher dose of 16mg/m2 which had also been cleared.
The company said that all new patients enrolled in the trial would receive the higher dose.
Bionomics said that individual patients had received up to 14 cycles of treatment with the combination of BNC105 and Afinitor.
Last month, Bionomics discontinued its 60-patient phase II BNC105 mesothelioma trial, but said the planned 134-patient, phase II trial of BNC105 for renal cell carcinoma would continue with the dose-ranging trial showing safety and tolerability (BD: Aug 3, 2011).
Today the company said it was conducting the US multi-centre clinical trial of BNC105 in combination with Afinitor, an mTOR inhibitor, which is used as a second line treatment after patients have failed first line therapy with tyrosine kinase inhibitors.
Bionomics said Afinitor was marketed by Novartis and had sales of $US192 million in the six months to June 30, 2011.
Bionomics said that five more clinical trial centres in the US had opened, taking the total to 14 sites and it expected 21 trial sites to be open by the end of October 2011.
Bionomics head of research and development Dr Gabriel Kremmidiotis said the company's prediction that BNC105 would be a compatible agent for a combination with Afinitor had "proven correct from a safety perspective".
"The combination of BNC105 with an mTOR inhibitor in treating renal cancer has the potential to represent an entirely new treatment paradigm for patients with this disease," Dr Kremmidiotis said.
Bionomics chief executive officer Dr Deborah Rathjen said it was the first time a vascular acting cancer drug had combined with Afinitor with no increase in side-effects.
"We also see a clear opportunity for combining BNC105 and Afinitor … in other cancer types in the future, broadening the commercial potential of BNC105," Dr Rathjen said.
Dr Rathjen said Afinitor was in trials in other cancers including breast and lung cancer.
Bionomics said renal cell carcinoma was the most common form of kidney cancer and was due to mutations of cells in the kidney's filtering system, with more than 100,000 people dying of renal cell carcinoma each year.
Bionomics said that data from the trial and a planned ovarian cancer trial would enable consideration by the US Food and Drug Administration of fast-track designation.
Bionomics was unchanged at 43 cents.

NOVOGEN

Novogen says 65 percent subsidiary Marshall Edwards has dosed the first patient in its phase I clinical trial of ME-143 for refractory solid tumors (BD: Aug 17, 2011).
Novogen said the trial, in collaboration with the Sarah Cannon Research Institute, was expected to enrol up to 24 patients with final data collected by the April 2012.
Novogen said the open-label, dose-escalation trial would evaluate the safety and tolerability of intravenous ME-143, characterize the pharmacokinetic profile of intravenous ME-143 and describe any preliminary clinical anti-tumor activity observed.
The company said that ME-143 was Marshall Edwards' nicotinamide adenine dinucleotide oxidase inhibitor program lead candidate.
Novogen said ME-143 had shown an ability to enhance the cytotoxic effects of chemotherapy in pre-clinical studies.
Novogen was untraded at 15 cents.

PROGEN PHARMACEUTICALS

Progen says its phase Ia PG545 trial in advanced cancer patients “has been put on hold due to unexpected local injection site reactions seen in patients”.
Progen said the reactions appeared to be a very specific side effect in humans and were not seen to this extent in the extensive preclinical animal testing of the drug.
The company said it had halted patient recruitment and would formally close the study once the current cohort of patients was completed.
Progen said that no significant systemic toxicities were observed at the doses administered, with the drug well-tolerated with the exception of the injection site reactions.
The company said it would review a potential change in the route of administration from subcutaneous to intravenous to address this issue.
Progen chairman Stuart James said while it was “a disappointing short term outcome PG545, remains an exciting new anticancer drug and we believe that with further development it will re-enter clinical trials in 2012”.
“PG545 is still potentially the best-in-class heparanase inhibitor with superior drug-like properties,” Mr James said. “We believe that it has the potential to extend and enhance the lives of cancer patients through its dual mechanism of action of stopping both tumor growth and tumor spread.”
The company said it would put on hold its plan to file an investigational new drug application to the US Food and Drug Administration until further data was available.
Progen was untraded at 21 cents.

PATRYS

Patrys says pre-clinical studies show that lead product PAT-SM6 may have efficacy against ovarian and prostate cancer.
Patrys said the best results were seen in a study of PAT-SM6 for ovarian cancer in mouse models conducted by Vivopharm Pty Ltd.
The company said that PAT-SM6 was tested in the OVCAR-3 human ovarian cancer model in which the reduction of tumor size was measured and compared to treatment with doxorubicin, a chemotherapeutic considered the standard-of-care for the disease.
Patrys said the OVCAR-3 model was widely used to assess the potential of novel therapies, with the cell line established from a patient with advanced ovarian cancer and the cells resistant to a range of chemotherapies.
Patrys chief executive officer Dr Marie Roskrow said the results were “very encouraging as they extend the preclinical data we already have for PAT-SM6 which shows binding to a wide range of tumor types and potency against multiple cancer cell lines”.
“To show efficacy in additional cancer models links that target binding data to activity and reinforces the commercial attractiveness of this product,” Dr Roskrow said.
“We now have excellent data in models of melanoma, metastatic colon, ovarian, lung, pancreatic, prostate and gastric cancers,” Dr Roskrow said.
“Positive data in a range of cancers allows Patrys to advance confidently with the planning of its phase I/IIa study for PAT-SM6, which will look at safety and efficacy across a range of tumors,” Dr Roskrow said.
“Including patients with additional cancer types means that recruitment into the trial will be open to a broad population, increasing the opportunity for patients with advanced disease to participate,” Dr Roskrow said.
“It also means that Patrys can expand the indications under investigation to give the product the best chance of success,” Dr Roskrow said.
Patrys was up 0.4 cents or 6.8 percent to 6.3 cents.

QRX PHARMA

Orbis Investment Management has increased its substantial holding in QRX from 9,785,634 shares (7.77%) to 12,960,965 shares (8.99%).
Orbis said it bought and sold shares between April 6 and September 16, 2011 with the largest purchase 844,601 shares for $1,094,681 or $1.296 a share.
In its last substantial shareholder notice for QRX in April, Orbis said it had sold 745,684 shares for $1,400,007 or an average price of $1.61 a share (BD: Apr 8, 2011).
In November 2010, Orbis acquired 4,511,322 shares for $3,832,427 in a placement at 85 cents a share.
QRX was unchanged at $1.12.

VIRALYTICS

Viralytics says Tom Rowe will replace Jennie Yuen as company secretary, effective immediately.
Viralytics said Ms Yuen and Mr Rowe both worked as solicitors for Company Matters Pty Ltd and the change was a continuation of the existing engagement between the company and Company Matters.
Viralytics fell 2.5 cents or 4.6 percent to 51.5 cents.