



Biotech Daily

Wednesday April 10, 2013

Daily news on ASX-listed biotechnology companies

- * **ASX DOWN, BIOTECH EVEN: PATRYS UP 25%, CIRCADIAN DOWN 7%**
- * **ANTISENSE BEGINS PHASE II ATL1103 FOR ACROMEGALY DOSING**
- * **PATRYS COMPLETES 2nd PAT-SM6 MULTIPLE MYELOMA COHORT**
- * **CORRECTION: BONE**
- * **JAPAN PATENT FOR AVITA'S RECELL**
- * **PHARMAXIS HIRES UNITED MEDICAL FOR BRONCHITOL IN BRAZIL**
- * **PHYLOGICA CONTRACTS NEW YORK'S GRIFFIN FOR POTENTIAL DEALS**
- * **BURNET VIROLOGY, IMMUNOLOGY MERGE FOR VACCINE DEVELOPMENT**

MARKET REPORT

The Australian stock market fell 0.18 percent on Wednesday April 10, 2013 with the S&P ASX 200 down 8.8 points to 4,968.0 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 12 fell, 11 traded unchanged and four were untraded. All three Big Caps fell.

Patrys was the best, up 0.6 cents or 25 percent to three cents with four million shares traded, followed by Antisense up 22.2 percent to 1.1 cents with 3.8 million shares traded and Uscom up 11.1 percent to 20 cents with 26,750 shares traded.

Pharmaxis climbed 4.7 percent; Alchemia and Allied Health were up three percent or more; Atcor rose 2.2 percent; Bionomics, GI Dynamics, Medical Developments and QRX were up more than one percent; with Clinuvel and Sirtex up by less than one percent.

Circadian led the falls, down two cents or 7.1 percent to 26 cents, with 1,950 shares traded.

Cellmid lost 5.7 percent; Avita and Nanosonics fell more than four percent; Tissue Therapies and Viralytics were down more than three percent; Living Cell, Prima and Psivida shed more than two percent; Acrux, Mesoblast and Resmed were down one percent or more; with Cochlear, CSL and Starpharma down by less than one percent.

ANTISENSE THERAPEUTICS

Antisense says that dosing has begun on schedule in its 24-patient phase II clinical trial of ATL1103 for the growth disorder acromegaly.

Antisense said that the ATL1103 phase II trial was a randomized, open-label, parallel group study of the safety, tolerability, pharmacokinetics and efficacy of two subcutaneous dosing regimens of ATL1103.

The company said that the trial was being conducted at 11 sites in the UK, Spain and France, with five trial sites in the UK and two in Spain initiated and ready to recruit patients and French sites to be initiated by June.

Antisense chief executive officer Mark Diamond said the “commencement of dosing is always a significant milestone in any clinical trial and is the culmination of a huge amount of work and dedicated effort by the ... team, our expert advisors, consultants and contractor network”.

Antisense was up 0.2 cents or 22.2 percent to 1.1 cents with 3.8 million shares traded.

PATRYS

Patrys says it has completed the initial treatment of the second group of patients in its phase I/IIa PAT-SM6 multiple myeloma trial (BD: Dec 10, 2012; Jan 20, Mar 7, 2013).

Patrys said that the second group of three patients was treated at Germany's University Hospital of Würzburg, with each patient receiving four doses of 1.0mg/kg PAT-SM6.

The company said that to date, no significant safety issues had been observed or reported for any of the three patients treated.

Patrys said that it was significant that one of the treated patients showed laboratory evidence of stable disease, at day-35 post-treatment, with a significant reduction in protein M levels in the peripheral blood.

The company said that the patient had multi-resistance, refractory disease and prior to inclusion into the trial had rapidly rising protein M levels, indicating progressive disease.

The University Hospital of Würzburg's Dr Leo Rasche said that all patients treated had “very advanced and rapidly progressing disease and we are delighted that one of them has shown stabilization of his disease”.

“In such resistant patients, this is a significant observation,” Dr Rasche said.

Patrys chief executive officer Dr Marie Roskrow said that the researchers continued “to observe excellent safety and tolerability in all of the patients that we have treated to date”.

“In addition, we are now observing definite signs of immunological responses in these patients indicating that PAT-SM6 is binding to the tumor cells and stimulating the immune system,” Dr Roskrow said.

Dr Roskrow said the company was “looking forward to treating the next cohort of patients as soon as possible”.

Patrys said the trial was an open-label, multi-dose, escalation trial in relapsed and multi-resistant patients with multiple myeloma who failed all currently marketed drugs and had a very poor prognosis.

The company said that 12 patients would be enrolled in four dosing groups and receive a minimum of two cycles or four doses of treatment.

Patrys said that if a patient showed a partial response to treatment with PAT-SM6 an additional cycle of two doses of treatment would be offered.

The company said that the primary objective of the study was to evaluate the safety and tolerability of escalating doses of PAT-SM6, with the secondary objective to measure efficacy.

Patrys was up 0.6 cents or 25 percent to three cents with four million shares traded.

BONE MEDICAL

Last night's edition reported on two separate Bone Medical trials, the first on BN006 for rheumatoid arthritis and the second on Capthymone for osteoporosis.

The original announcement did not specify the stage of each trial explicitly and when Bone chief executive officer Peter Young told Biotech Daily that the trial was an eight-patient, phase I randomized, cross-over design study, that description was attributed to the first trial, BN006.

Overnight, Mr Young said that the BN006 trial was an in-vivo, proof-of-concept trial in a collagen antibody induced arthritis experiment in mice, a widely accepted standard disease model for rheumatoid arthritis.

The eight-patient, phase I clinical trial was the Capthymone pharmacokinetic study for osteoporosis.

No sub-editors were hurt in making this correction.

Bone fell 0.1 cents or 50 percent to 0.1 cents with 36.4 million shares traded.

AVITA MEDICAL

Avita says that Japan has granted a patent entitled 'Cell Suspension Preparation Technique and Device' protecting its Recell Spray-On-Skin technology.

Avita said that Japan was the world's third largest healthcare market behind the US and Europe with the longest life expectancy and an ageing population.

The company said that the patent protected broad claims related to the preparation and composition of a cell suspension comprised of the patient's own epithelial cells, an autologous suspension, and the general therapeutic use of the regenerative epithelial cell suspension.

Avita said that the patented technology was incorporated into lead product, Recell Spray-On-Skin, used in the treatment of chronic and acute wounds and a wide range of reconstructive and aesthetic procedures.

Avita research and technology vice-president Andrew Quick said the Japanese patent added to granted patents in Europe, the US and Australia.

Avita fell half a cent or 4.35 percent to 11 cents.

PHARMAXIS

Pharmaxis says it has appointed the São Paulo-based United Medical as its distributor and sales representative for Bronchitol in Brazil.

Pharmaxis said that United Medical had responsibility for sales and marketing, pricing, warehousing, distribution and patient support and would file a marketing approval application with the Brazilian regulatory agency based on Bronchitol's Australian approval, a process expected to take up to 18 months.

Pharmaxis said it would receive milestone payments ahead of approval in Brazil.

Pharmaxis chief executive officer Gary Phillips said that Brazil had about 3,500 cystic fibrosis patients with 32 specialist treatment centres "and a well-funded reimbursement scheme providing access to new medications".

The company said United Medical had a suite of products associated with the cystic fibrosis market including an inhaled antibiotic, specific pancreatic enzymes and vitamins.

United Medical chief executive officer Roberto Guttmann said Bronchitol was "an important tool for physicians, being at the same time a simple innovative and well rounded solution to achieve a better quality of life for cystic fibrosis patients".

Pharmaxis was up 1.5 cents or 4.7 percent to 33.5 cents with 1.85 million shares traded.

PHYLOGICA

Phylogica says it has engaged New York investment bank Griffin Securities, to evaluate “strategic opportunities available to the company”.

Phylogica chief financial officer Nick Woolf told Biotech Daily that Phylogica had “received specific interest from several companies and was investigating other opportunities”.

In a media release Phylogica chief executive officer Dr Paul Watt said that the company had demonstrated “the value of our Phylomer platform through the progress of our four alliances with top-10 pharmaceutical companies”.

Dr Watt said Phylogica had validated the Phylomer approach and established the technology at the forefront of peptide drug discovery, with potential applications in animal health, agricultural biotech and industrial products.

“As a result, Phylogica has caught the attention of companies wanting to access our next generation peptide drug discovery capabilities, but also companies that are interested in additional uses of the platform,” Dr Watt said.

“We have had informal approaches from several companies and have also stimulated interest from a number of pharmaceutical corporate venture divisions,” Dr Watt said.

Griffin Securities founder and chief executive officer Adrian Stecyk said the Phylomer platform was “a world-changing technology” and his company would explore strategic options including: broad therapeutic discovery alliances; partnerships spanning other applications of the platform such as animal health, agriculture and industrial; and, strategic opportunities with companies with synergistic technology.”

Phylogica was unchanged at 1.9 cents with 100 shares traded.

THE BURNET INSTITUTE

The Burnet Institute says it will integrate two basic science divisions, virology and immunology, into a new Centre for Biomedical Research to improve vaccine development. The Burnet said that the centre would be based at its Melbourne headquarters and would have more than 120 researchers, working with students in clusters of research disciplines “in a highly competitive, innovative and cutting edge environment”.

Burnet director and chief executive officer Prof Brendan Crabb said the Centre was “an important step forward”.

“The new Centre will further invigorate our laboratory-based research programs and provide many new opportunities for growth, cross-disciplinary collaboration, leadership and success,” Prof Crabb said. It will also provide a means to expand our non-virus infectious disease research, such as tuberculosis and malaria, which are diseases of enormous global health significance.”

The Burnet Institute said that Prof James Beeson and Prof Sharon Lewin would lead the Centre for Biomedical Research.

“The Centre will have a broad research program on infectious diseases, autoimmune and inflammatory diseases, and cancer, as well as research into understanding how the immune system fights infectious diseases and cancer, or malfunctions in auto-immune diseases,” Prof Beeson said.

The Burnet said the aim was to develop new treatments, vaccines, diagnostics and prevention strategies for diseases including HIV, malaria, hepatitis C, tuberculosis and influenza, as well as arthritis and lupus, and breast, ovarian, cervical and prostate cancer.