Biotech Daily

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Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ELLEX UP 25%, SUNSHINE HEART DOWN 20%**

*** ANTISENSE, TIANJIN JV TAKES ATL1102 BACK TO CLINIC FOR MS**

*** CE MARK FOR ELLEX 2RT LASER TREATMENT**

*** BIOTECH TAKES 5 OF 6 VICTORIA GRANTS - UP TO $1.5m EACH**

*** ALNYLAM RNAi SUCCESS 'GOOD FOR BENITEC'**

*** US AXCESS III PATENT FOR BONE**

*** PHARMAXIS BRONCHITOL SALES BEGIN, R&D PIPELINE DETAILED**

*** CIRCADIAN COMPANIES INCREASE, DILUTED TO 11% IN ANTISENSE**

*** ROBERT TOWNER TAKES 6% OF NEURODISCOVERY**

MARKET REPORT

The Australian stock market fell 0.42 percent on Wednesday July 18, 2012 with the S&P ASX 200 down 17.2 points to 4,123.6 points.

Nine of the Biotech Daily Top 40 stocks were up, 13 fell, 12 traded unchanged and six were untraded. All three Big Caps were up.

Ellex was the best, up four cents or 25 percent to 20 cents, with 27,555 shares traded.

Benitec climbed 5.9 percent; Prima was up 4.8 percent; Anteo rose 2.7 percent; Bionomics, Clinuvel, Cochlear and CSL were up more than one percent; with Biota, Heartware, Resmed and Starpharma up by less than one percent.

Sunshine Heart led the falls for the second day in a row, down one cent or 20 percent to four cents with 701,000 shares traded, followed by Phylogica down 11.9 percent to 3.7 cents with 919,418 shares traded.

Antisense lost 9.5 percent; Cellmid fell 6.7 percent; Avita was down 5.3 percent; Circadian and Pharmaxis fell more than four percent; Reva was down 3.45 percent; Acrux shed 2.9 percent; Alchemia and Universal Biosensors were down more than one percent; with QRX down 0.7 percent.

ANTISENSE THERAPEUTICS

Antisense will proceed with its joint venture with Tianjin International Joint Academy of Biotechnology and Medicine to develop ATL1102 initially for multiple sclerosis.

In February, Antisense said it would form a joint venture with Tianjin to develop and commercialize ATL1102 for multiple sclerosis, stem cell mobilization and asthma (BD: Feb 29, 2012).

Antisense previously licenced ATL1102 to Israel's Teva following statistically significant phase II trial results for multiple sclerosis, but Teva later returned the drug (BD: Jun 30, 2008; Mar 24, 2010).

Today, Antisense said the strategic alliance and joint venture would see Tianjin take responsibility for the costs of developing ATL1102 and would be responsible for commercialization in China and Hong Kong, while Antisense would provide the intellectual property and be responsible for its commercialization in the rest of the world.

The company said it would own 49 percent of the joint venture and Tianjin would own 51 percent, with any income derived from the commercialization of ATL1102 based on agreed splits that varied on the level of investment made by TJAB and its investors for product development and in what countries the commercialization benefits were generated.

Antisense said Tianjin would earn between 50 and 80 percent in China and Hong Kong with 20 to 50 percent to Antisense, while it would earn 65 to 90 percent in the rest of the world, with Tianjin taking 10 to 35 percent.

The company said there were "certain conditions precedent that must be met before the agreement comes into full operation and development activities can commence" including a shareholders' agreement and arrangements with third parties related to ATL1102 intellectual property and the supply of raw material.

Antisense said it would not be required to provide any funding towards the development activities of the joint venture company, which were expected to begin by October 2012.

Antisense said the initial development activities would be accessing ATL1102 raw material and formulating it material into injectable product for use in a planned chronic toxicology study in one species to support a phase IIb study of ATL1102 in multiple sclerosis patients.

In 2008, Antisense said that 76 patients were dosed with either ATL1102 or placebo in the randomized, double-blind, phase IIa clinical trial with subcutaneously injections and, in general, ATL1102 was well-tolerated (BD: June 30, 2008).

The company said at that time that potentially attributable adverse events included injection site reactions which were mild to moderate and thrombocytopenia, or a decrease in platelets in the blood, which was reversible after treatment interruption returning to within normal ranges and was not accompanied with any clinical consequences.

Antisense managing director Mark Diamond told Biotech Daily that when Teva handed back ATL1102 it had said a further toxicology study would be required.

Mr Diamond said the animal species to be used in the study had not been disclosed.

In the media release the company said that other development activities included a first-in-man stem cell mobilization study and a potential phase II study in asthma patients.

Tianjin senior vice-president Prof Yao-Zhou Zhang said his Academy was "excited to be co-operating in the joint development of ATL1102 which we believe has significant commercial potential".

"The chronic toxicology study will be conducted in China at one of our leading contract research organizations with whom we have a close association," Prof Zhang said.

Mr Diamond said Antisense was "very pleased" to return ATL1102 to development.

Antisense fell 0.2 cents or 9.5 percent to 1.9 cents with 70.3 million shares traded.

ELLEX MEDICAL LASERS

Ellex says it has been granted Conformité Européenne (CE) mark for its 2RT pain and damage-free retinal rejuvenation therapy.

Ellex said the 2RT delivered nanosecond pulses of laser energy to stimulate biological healing in the eye to treat retinal disease, allowing therapeutic benefit to be achieved without the thermal damage and pain associated with conventional retinal laser treatment.

Ellex chief executive officer Tom Spurling said the CE mark had "a global significance … [and] the 2RT therapy materially changes the decision making process of patients and ophthalmologists faced with the prospect of retinal treatment with a laser".

"We expect that 2RT therapy will radically alter the risk benefit assessment of patients by ophthalmologists," Mr Spurling said.

Mr Spurling said the CE mark facilitated sales in Europe, Australia, New Zealand as well as countries in South East Asia, the Middle East and South America and was the foundation for registration in Japan and China.

Ellex said that European ophthalmologists would be able to use the 2RT to treat diabetic macular oedema, a common symptom of diabetic retinopathy that caused a decrease in visual acuity.

Ellex said the 2RT was also undergoing clinical trials for the treatment of early age-related macular degeneration, the leading cause of blindness in the developed world.

Ellex was up four cents or 25 percent to 20 cents.

VICTORIA GOVERNMENT

Victoria's Minister for Innovation and Small Business Louise Asher says six businesses will receive up to $1.5 million each for innovation proof-of-concept activities.

Ms Asher said the funds would come from the Smart Small and Medium Enterprises Market Validation Program, a $28 million competitive grants program that sought to engage with government and business to promote innovation

Ms Asher said the program assists small and medium businesses to develop innovative products, processes and services that meet the needs of Victorian Government agencies, and have the potential to find wider markets for participating businesses.

A Victoria government media release said that Osprey Medical would work with Melbourne Health to develop an antibiotic delivery system to manage diabetes-related foot disease.

Earlier this month, Osprey said it had received a $1.1 million grant from the Victorian Government's Market Validation Program to conduct a first-in-man clinical study on its percutaneous limb perfusion technology (BD: Jul 4, 2012).

The Victoria Government said Genes FX would work with Melbourne Health to develop an innovative drug safety system to reduce adverse reactions; Ingeneus would work with the Royal Victorian Eye and Ear Hospital to develop a portable slit lamp for use in the treatment of glaucoma; APS Innovations would work with the Royal Children's Hospital to develop a specialized infant feeding teat for both healthy and difficult feeders; Alcidion would work with Western Health to develop an innovative software platform for management of patient stays in hospitals; and Hawk Measurement would work with Melbourne Water to develop fibre optic products for water pipelines;

"This round of funding will enable businesses to develop new projects that have the potential to result in greater productivity with more efficient and effective ways of doing things," Ms Asher said.

"The program targets the procuring power of government as a basis to stimulate and create a capacity for small businesses to innovate," Ms Asher said.

BENITEC BIOPHARMA

Benitec says Alnylam Pharmaceuticals' RNAi-based ALN-TTR02 showed significant efficacy in a phase I trial for transthyretin-mediated amyloidosis.

Benitec said that it and the Cambridge, Massachusetts-based Alnylam had a cross-licencing agreement for the use of each other's technologies for up to five gene targets.

According to Alnylam's website, the phase I trial gave positive clinical results with ALN-TTR02, an RNAi therapeutic targeting the transthyretin (TTR) gene for the treatment of TTR-mediated amyloidosis, with the data presented in a seminar by Alnylam scientists at Boston University School of Medicine.

Benitec said Alnylam were developing medical therapies using a non-competing RNAi gene silencing technology called short interfering RNA or siRNA.

Benitec chief executive officer Dr Peter French said the positive early stage data and progress for Alnylam's non-competing gene silencing technology "makes encouraging news for all companies in the RNA interference space, particularly as a phase II study has already started".

"We believe this good news further validates our risk-managed business and clinical development model to commercialize our proprietary gene silencing platform technology, ddRNAi," Dr French said.

Dr French said the main differences between Alnylam's use of the synthetic siRNA approach to silence genes and Benitec's DNA-directed interference (ddRNAi) approach were primarily that ddRNAi couldn provide very long term gene silencing from a single treatmen, and that technologies were widely available to allow efficient delivery of ddRNAi-based drugs to a wide range of organs, not only the liver.

Benitec said that at the highest dose, a single administration of ALN-TTR02 reduced the protein that caused the disease by as much as 94 percent in 17 healthy volunteers.

Benitec said Alnylam reported no serious adverse events or discontinuations in the patient group and following the news, Alnylam's shares rose 50 percent to a two-year-high.

The company said that Alnylam's treatment targeted the mutated TTR gene which caused a harmful accumulation of the protein in the heart, nervous system and gastrointestinal tract.

Benitec said the disease was caused by a mutation in the gene responsible for producing the transthyretin protein and in people with the genetic defect, transthyretin made by the liver broke apart, formed into clumps and damaged the nerves and heart.

The company said that at present a liver transplant was the only available treatment.

Benitec was up 0.1 cents or 5.9 percent to 1.8 cents with 14.2 million shares traded.

BONE MEDICAL

Bone says it has been granted a US patent for its Axcess III oral peptide formulation technology.

Bone chairman, chief scientific officer and the inventor of the Axcess technology Dr Roger New said the patent was "a major milestone" in the development of the technology.

"Axcess III addresses the version of this technology that we use in Capsitonin, our proprietary oral calcitonin product for osteoporosis and arthritis pain," Dr New said.

"The US patent grant not only cements the protection of the intellectual property that is such a critical prerequisite for the development of new medicines, but it is a significant sign of the credibility and novel inventiveness of this platform," Dr New said.

Bone said it had licenced the rights in musculoskeletal diseases to the Axcess oral peptide technology platform from Proxima Concepts, a company related to Dr New.

Bone was unchanged at 0.5 cents with 39.3 million shares traded.

PHARMAXIS

Pharmaxis chief executive officer Dr Alan Robertson says sales of Bronchitol for cystic fibrosis are underway, with the company also preparing for the bronchiectasis indication.
In a quarterly teleconference Dr Robertson described the sales and marketing efforts required to take Bronchitol to patients, including visits to specialist clinics, training clinicians in the use of Bronchitol and then take up by pharmacies and patients.
Dr Robertson said Pharmaxis had 56 patients at the end of June and 90 patients in July.
Dr Robertson said the sales team had visited most of the 134 German centres and had been actively pursuing the 27 UK centres.
Dr Robertson said there had been delays due to the reimbursement approval process at the UK National Institute for Health and Clinical Excellence, which he expected to be finalized by the end of this year, but despite the delay some hospitals were considering the use of Bronchitol.
Dr Robertson said Bronchitol was approved in 29 countries in Europe and the roll-out would proceed to Austria, Denmark and Ireland ahead of France, Spain and Italy.
Dr Robertson said the new drug application for Bronchitol, for people with cystic fibrosis over the age of six years, had been filed to the US Food and Drug Administration in May 2012 with about 10 months for the FDA to make a decision, with a review date from the FDA expected “in the next few weeks”.
Dr Robertson said he was pleased that Bronchitol was approved and reimbursed in Australia, noting the drug first began development in Sydney 15 years ago and its development had been supported by government grants and Australian shareholders.
Dr Robertson detailed the company’s research and development pipeline to the teleconference and said the 485-patient phase III trial of Bronchitol for the second indication of bronchiectasis was fully recruited and closed, with the last patient expected to complete dosing early in 2013 with results to follow “shortly after”.
Dr Robertson said that along with ASM8 for asthma and PXS64 for lung fibrosis the company had added the oral anti-inflammatory drug PXS4728A to its development pipeline and it was scheduled to begin phase I trials in 2013.
He said PXS4728 had potential application in inflammatory lung diseases including asthma and chronic obstructive pulmonary disease as well as macular degeneration and fibrosis.
Dr Robertson said the Aridol asthma test earned $373,000 in revenue in the three months to June 30, 2012, primarily from the US and South Korea.
Pharmaxis fell 4.5 cents or 4.1 percent to $1.05.

ANTISENSE, CIRCADIAN

Two Circadian-related companies have been diluted in and one has decreased its substantial holding in Antisense.
The total change is from 135,915,909 shares (11.98%) to 143,149,187 shares (11.03%).
The companies were Circadian’s wholly-owned subsidiary Polychip Pharmaceuticals and Polychip’s 51.67 percent subsidiary Syngene.
Polychip’s 101,906,497 shares were diluted from 8.98 percent to 7.85 percent, while Syngene increased from 34,009,412 shares (3.00%) to 41,242,690 shares (3.18%).
Circadian has previously told Biotech Daily (BD: Feb 5, 2010) that the Packer family Consolidated Press Holdings held 19.9 percent of Syngene and the Howard Florey Institute owned about 20 percent, with the remainder owned by about 40 other holders.
Antisense recently raised $5 million at 1.8 cents a share (BD: May 4, 2012).
Circadian fell two cents or 4.8 percent to 40 cents.

NEURODISCOVERY

Robert Towner and related entities have become substantial shareholders in Neurodiscovery with the acquisition of 5,760,401 shares or 5.941 percent.
The initial substantial shareholder notice said the shares were acquired for $139,822 or 2.4 cents a share.
Former Allied Health and Biomd director Mr Towner said the related parties were Austin 4 Pty Ltd and Mandolin Pty Ltd.
Neurodiscovery was untraded ay 2.5 cents.