Biotech Daily

Wednesday May 5, 2010

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: SUNSHINE HEART UP 20%; LIVING CELL DOWN 14%**

*** VICTORIA INVESTS $650k IN BACE ALZHEIMER'S DISEASE TREATMENT**

*** VICTORIA PROVIDES $540k FOR ELLEX 2RT TRIAL**

*** QRX SAYS DATA BACKS MOXDUO DESPITE INCREASED VOMITING**

*** PBS LISTS MEDICAL DEVELOPMENTS PENTHROX**

*** GENETIC TECHNOLOGIES NON-CODING DNA LICENCE FOR ERAGEN**

*** VICTORIA ESTABLISHES BIOELECTRONICS LAB FOR BIONIC EYE**

*** SUNSHINE HEART IMPLANTS 6th PATIENT**

*** MESOBLAST EXTENDS MERGER ACQUISITION HALT TO SUSPENSION**

MARKET REPORT

The Australian stock market fell 1.33 percent on Wednesday May 5, 2010 with the S&P ASX 200 down 63.1 points to 4674.0 points.

Just five of the Biotech Daily Top 40 stocks were up, 24 fell, five traded unchanged and six were untraded.

Sunshine Heart was best, up 0.6 cents or 20 percent to 3.6 cents with 2.1 million shares traded followed by Resmed up 1.5 percent to $7.47 with 1.6 million shares traded, Heartware up 1.2 percent to $1.71 and Cellestis up 1.02 percent to $2.98.

Living Cell led the falls, down 5.5 cents or 14.1 percent to 33.5 cents with 1.3 million shares traded, followed by Compumedics down two cents or 11.8 percent to 15 cents and LBT down one cent or 11.1 percent to eight cents on small volumes.

Patrys and Prana both fell 8.3 percent; Avexa and Tissue Therapies both lost 7.7 percent; Prima was down 6.25 percent; Antisense and Nanosonics fell more than five percent; Benitec and Psivida were down more than four percent; Bionomics, Biota, Novogen and Universal Biosensors were down more than three percent; Chemgenex, Clinuvel, Sirtex and Viralytics shed more than two percent; with Circadian, Cochlear and QRX down more than one percent.

VICTORIA GOVERNMENT, BACE, WEHI, MHRI, UNIVERSITY OF MELBOURNE

The Victoria Government has provided $650,000 to Bace Therapeutics to develop a drug to block beta secretase in Alzheimer's disease patients.

The Government media release said Bace Therapeutics was made up of scientists from the Walter and Eliza Hall Institute of Medical Research, the University of Melbourne and the Mental Health Research Institute.

Innovation Minister Gavin Jennings said the drug had the potential to block the progress of Alzheimer's disease and the funds would assist in the drug's preclinical development.

Mr Jennings said the funding was through the Medical Research Commercialisation Fund, a fund established with support from the Victorian and New South Wales Governments.

"Victorian scientists were the first in the world to demonstrate that the enzyme beta secretase is increased in the brain cortex of Alzheimer's patients," Mr Jennings said.

"They are now working to develop drugs that block this enzyme," Mr Jennings said.

"The process of getting drugs to the clinical trial phase can be very expensive which is why it is important the Government helps through funding such as this," he said.

The media release said Bace's investment and research program built on the findings of the Walter and Eliza Hall Institute for Medical Research's Dr Brian Smith, who discovered two compounds that bind to beta secretase, also called Bace1.

Further development of these compounds was done in collaboration with the University of Melbourne's Dr Genevieve Evin, Dr Kevin Barnham and Dr Vijaya Kenche.

"Beta secretase appears to be directly involved in the early development of Alzheimer's disease. Blocking this enzyme would hopefully also block progression of the disease," Dr Smith said.

The media release said Dr Evin was the first to show that beta secretase was increased in the brain cortex of Alzheimer's patients and had shown that the two compounds identified by Dr Smith were effective at inhibiting beta secretase.

The market for Alzheimer's therapeutics was expected to be worth $7.2 billion in 2010.

The principal executive of the Medical Research Commercialisation Fund Dr Chris Nave said the research teams from WEHI, the University of Melbourne and the Mental Health Research Institute were recognized internationally as leaders in the fight against Alzheimer's and related neurodegenerative disorders.

"This research represents another excellent example of the high-quality, early stage investment opportunities that arise from Australia's medical research institutes and is a further demonstration of the benefits of the MRCF Collaboration, which now includes 27 medical research institutes and research hospitals across Australia," Dr Nave said.

VICTORIA GOVERNMENT, ELLEX MEDICAL LASERS

The Victorian Government says it is providing $540,000 for the Ellex and Centre for Eye Research Australia retina regeneration therapy (2RT) trial reported in yesterday's edition.

The Victorian Government said the funds from the $41 million Victoria's Science Agenda Investment Fund were for a laser treatment for age-related macular oedema.

Innovation Minister Gavin Jennings said that 500,000 Australians or 15 percent of people over 50 years of age, lived with the early stages of the disease, which was the leading cause of vision loss in Australia, estimated to cost more than $2.6 billion a year.

Mr Jennings said the Retina Regeneration Therapy would be trialed on 50 patients and of the 14 to have undergone the treatment so far most had shown signs of improvement in the degenerative state of the retina (BD: May 5, 2010.

"The results so far are extremely exciting," Mr Jennings said.

Ellex fell half a cent or 3.2 percent to 15 cents.

QRX PHARMA

QRX says phase III immediate release Moxduo IR dual opiate trial data shows the combination is stronger than the components with generally equivalent side effects.

QRX has previously explained that the oxycodone in Moxduo blocks the nausea and vomiting receptors to morphine, so that the patient only has one dose of side-effects while receiving the benefit of both opioids (BD: Apr 29, 2009).

In a media release late yesterday, QRX said Moxduo IR "not only demonstrated statistically superior analgesic effect compared to component doses of morphine (p=0.01) and oxycodone (p=0.01) but, also, a favorable side effect profile despite delivering twice the opioid dose of its individual components.

QRX said the most common moderate to severe adverse events were dizziness, somnolence, nausea, vomiting, itchiness and skin rash.

The company said that the percentage of patients in the Moxduo IR group who reported moderate to severe vomiting was less than in previous studies and this was the only side effect that occurred more frequently with Moxduo IR than its half-dose components.

QRX did not provide tabulated data from the trial.

QRX said the combination rule, post-bunionectomy pain trial enrolled 522 patients at six US clinical research sites and compared Moxduo IR containing 12mg morphine and 8mg oxycodone with 12mg morphine in one cohort and 8mg oxycodone in another cohort.

QRX said the FDA did not require morphine equivalence be tested in the trial.

QRX chief executive officer Dr John Holaday said that while the initial trial data "demonstrated the superiority of Moxduo IR in terms of analgesic effect, further analysis revealed equally important findings in terms of superior overall pain relief, reduced reliance on supplemental analgesia and strong tolerability".

QRX said the primary endpoint was the difference in pain intensity scores from baseline for each patient over the 48-hour treatment period (SPID48).

QRX said secondary endpoints included efficacy relating to the amount of supplemental analgesic (ibuprofen) used; difference in pain scores over the first 24-hour treatment period; and safety measured by incidence and intensity of opioid-related adverse effects.

Patients in the control groups were two to three times more likely to use supplemental ibuprofen than those receiving Moxduo IR ($p<0.05$ to $p<0.01$) and were more likely to use ibuprofen in greater amounts and earlier than Moxduo IR patients ($p<0.01$ to $p<0.001$).

QRX said that even with ibuprofen, at both 24 and 48 hours, the control groups' pain reduction was significantly less than patients receiving Moxduo IR ($p<0.05$ to $p<0.001$).

The company said the reduced side effects of Moxduo IR seen in earlier studies was further validated in the trial.

Whilst patients in the Moxduo IR cohort received twice the morphine equivalent dose of patients in the other two comparator arms, the incidence and intensity of moderate to severe side effects was similar, QRX said.

The company said the tolerability was evidenced by the 93 percent to 95 percent patient completion rate in the study treatment groups.

"By delivering twice the opioid dose, one would expect a substantial increase in both the incidence and intensity of a broad range of side effects, but that is not the case with Moxduo IR," Dr Holaday said.

"Our dual-opioid formulation provides improved pain relief and greater tolerability as each drug component acts on different receptors," Dr Holaday said.

"This means we can enhance analgesia without significantly increasing side effects," Dr Holaday said.

QRX fell two cents or 1.7 percent to $1.17.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says its Penthrox methoxyflurane inhaler has been included in the Pharmaceutical Benefits Scheme emergency doctor's bag section, from May 1, 2010.
The company said the inclusion in the PBS would allow the free supply of Penthrox to general practitioners and was expected to result in a significant increase in use.
Medical Developments chief executive officer John Sharman said the direct inclusion of Penthrox in the doctors' bag section of the PBS "is a first of this type of listing and provides the opportunity for general practitioners to use the product for the management of acute pain rather than referring their patient to hospital emergency departments".
Biotech Daily has been advised that general practitioners usually carry morphine and other analgesics in their emergency bags.
One practitioner said that Penthrox would be a welcome addition, but would not replace morphine, which is also used for specific cardiac treatments.
Medical Developments chairman David Williams said Nycomed had been appointed distributors, had trained staff and conducted focus groups with doctors.
The company said Penthrox was used in all Australian ambulance services, the Australian Defence Forces, in sports medicine and for analgesia in dentistry and aesthetic surgery.
Medical Developments was up four cents or 23.5 percent to 21 cents.

GENETIC TECHNOLOGIES

Genetic Technologies has licenced its non-coding DNA patents to the Madison Wisconsin-based Eragen Biosciences for an undisclosed amount.
Genetic Technologies said the licence covered the activities of Eragen in relation to its genetic diagnostic and analysis products, limited to the US and Canada.
Genetic Technologies said that although not a counterparty to the US patent infringement suit (BD: Feb 16, 2010), discussions with Eragen had been proceeding for some time and resulted in a non-exclusive licence for all Eragen products, as well as the normalization of past historical sales by Eragen.
The company said that discussions with other parties both in the context of the patent infringement suit and external to that suit are ongoing and progressing.
Genetic Technologies was untraded at 4.4 cents.

VICTORIA GOVERNMENT

Victoria is establishing a bioelectronics laboratory to help develop an advanced bionic eye.
Innovation Minister Gavin Jennings said the laboratory would be set up by the National Information and Communications Technology Australia (NICTA) Victoria Research Laboratory at the University of Melbourne to design and test the advanced electronics included in the bionic eye, enabling patients to recognize faces and read large print.
Mr Jennings said the Victorian Government had invested $28 million into NICTA since 2004 as part of its commitment to developing cutting-edge infrastructure and establishing Melbourne as one of five leading global biotechnology hubs.
The laboratory will have software tools and circuit test and measurement equipment.
The facility's first project will be to design the advanced electronics behind the second prototype device to be developed by Bionic Vision Australia.
NICTA has collaborations including a cancer cell tracking initiative developed with the Walter and Eliza Hall Institute and software tools developed with the Peter MacCallum Cancer Centre that uses molecular tissue markers for cancer diagnosis and the prediction of responses to treatment.

SUNSHINE HEART

Sunshine Heart says Pennsylvania State University has implanted the company's sixth C-Pulse heart assist system in a patient.

Sunshine Heart said the patient was progressing "as expected" was the first implanted at Pennsylvania State University.

Sunshine Heart was up 0.6 cents or 20 percent to 3.6 cents with 2.1 million shares traded.

MESOBLAST

Mesoblast has requested a suspension to follow on from the trading halt requested on May 3, 2010 relating to a proposed merger or acquisition.

Mesoblast last traded at $1.935.