Biotech Daily

Wednesday April 11, 2012

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PRANA UP 6%, USCOM DOWN 17%**

*** QRX CLAIMS MOXDUO CR PHASE I SUCCESS; TABLETS RESIST TAMPER**

*** SIRTEX CLAIMS MARCH QUARTER DOSE SALES UP 34%**

*** NOVOGEN, MARSHALL EDWARDS READY FOR ME-344 TUMOR TRIAL**

*** CANADIAN PATENT FOR PRIMA'S CVAC OVARIAN CANCER VACCINE**

*** US PATENT FOR BPH, MOLECULAR DISCOVERY'S TUMOR SUPPRESSOR**

*** UBS AG TAKES 5% OF PHARMAXIS**

*** DR MERVYN JACOBSON REDUCES TO 29% OF GENETIC TECHNOLOGIES**

*** CHAIRMAN MEL BRIDGES BUYS 500k GENETIC TECHNOLOGIES SHARE**

MARKET REPORT

The Australian stock market fell 1.08 percent on Wednesday April 11, 2012 with the S&P ASX 200 down 46.2 points to 4,246.1 points.

Just three of the Biotech Daily Top 40 stocks were up, 20 fell, 11 traded unchanged and six were untraded.

Prana was the best, up one cent or 6.25 percent to 17 cents with 3,000 shares traded, followed by Sirtex up 5.85 percent, Alchemia up two percent and CSL up 0.4 percent.

Uscom led the falls, down 1.5 cents or 16.7 percent to 7.5 cents, with 26,600 shares traded, followed by Cellmid down 7.1 percent to 1.3 cents with 859,007 shares traded.

Bioniche, Genetic Technologies and Phosphagenics lost more than six percent; Antisense was down 5.6 percent; Prima fell 4.3 percent; Mesoblast and Phylogica were down more than three percent; Acrux, Anteo, Avita, Biota, Nanosonics, QRX and Universal Biosensors shed two percent or more; Cochlear, Pharmaxis and Tissue Therapies were down one percent or more; with Clinuvel, Resmed and Starpharma down by less than one percent.

QRX PHARMA

QRX says it has completed two phase I studies in healthy volunteers for Moxduo CR, a controlled-release dual-opioid using a three-to-two ratio of morphine and oxycodone.

QRX said the proprietary Moxduo CR formulation had sustained delivery technology as well as abuse deterrent and tamper resistant features and was designed to provide at least 12 hours of analgesia in patients suffering from moderate to severe chronic pain including cancer, lower back, osteoarthritis and neuropathic pain.

The company said the two clinical trials compared blood levels of Moxduo CR's components to Purdue Pharma's Oxycontin and MS Contin and demonstrated superior results, with sustained blood levels for up to 24 hours.

QRX said that further studies indicated Moxduo CR's increased resistance to tampering.

QRX chief executive officer Dr John Holaday said the "successful completion of these trials confirms the advantages of this formulation and enables QRX Pharma to initiate phase II proof-of-concept clinical studies mid-year 2012".

"These data suggest Moxduo CR may be positioned as a once or twice per day formulation for treating chronic pain, with the potential advantage of significantly reduced side effects as witnessed with immediate release Moxduo," Dr Holaday said.

"In the US alone, the chronic opioid pain market is a $US6 billion a year opportunity," Dr Holaday said.

QRX said the two phase I trials in healthy volunteers evaluated the rate at which key components of the Moxduo controlled-release formulation were absorbed, distributed, metabolized and eliminated by the body.

The company said that the first study compared Moxduo CR (30mg morphine sulphate and 20mg oxycodone) to the pharmacokinetic profiles of the same doses of MS Contin (30mg morphine) and, separately, Oxycontin (20mg oxycodone) in 10 healthy adult human subjects using a three-way crossover design.

QRX said that the pharmacokinetic results from the measurement of opioid blood levels over time showed a Moxduo CR profile consistent with expectations for a once to twice-daily formulation.

The company said the second study demonstrated that food consumption did not alter the pharmacokinetic profiles of morphine and oxycodone from Moxduo CR (30mg/20mg) tablets using a two-way crossover design with 17 healthy volunteers.

QRX said that to demonstrate the effects of chronic use on steady-state blood levels, the study also measured the repetitive-dose pharmacokinetic profiles of morphine and its metabolites as well as oxycodone during twice daily administration of Moxduo CR tablets for five days.

The company said that Moxduo CR tablets used in the clinical tests included its proprietary abuse deterrence formulation technology and as an indication of tamper resistance, attempts to extract morphine or oxycodone by crushing and solubilising in water or alcohol resulted in very limited (less than 15%) drug recovery.

In addition, the technology did not impair human bioavailability of the opioids following oral administration.

QRX chief operating officer Ed Rudnic said that the clinical performance of the oral Moxduo CR formulation "clearly exceeded our expectations …[demonstrating] superior bio-availability and sustained blood levels for over 12 hours, especially in the 12-24 hour time period" and at steady-state, Moxduo CR provided very low fluctuations of oxycodone.

QRX said its US partner for Moxduo IR, Actavis Inc, had the option to negotiate for the US licence of Moxduo CR pending Moxduo IR sales milestones and it expected to launch Moxduo CR in the US chronic pain market in 2015.

QRX fell four cents or 2.3 percent to $1.71.

SIRTEX MEDICAL

Sirtex says dose sales of its SIR-Spheres liver cancer treatment were up 34 percent for the three months to March 31, 2012 compared with the same quarter last year.

Sirtex has previously said that dose sales were its "key metric of business growth" but did not publish the number of doses sold.

Sirtex previously reported that for the year to June 30, 2011 it sold 4,977 doses earning revenue of $70.3 million; and a 16 percent growth in dose sales for the six months to December 31, 2011 to 2,698 units (BD: Aug 25, 2011; Feb 29, 2012), with dose sales priced at $8,500 in Australia, EUR12,000 in Europe and $US15,000 in the US.

Today, Sirtex chief executive officer Gilman Wong said the result was "the largest increase in the number of doses sold in a quarter achieved by Sirtex in its history".

"It is pleasing to see our strategy of making appropriate investments in the company, sales and marketing, clinical studies and research continues to deliver consistent growth of SIR-Spheres microspheres and building a robust sustainable business," Mr Wong said.

Sirtex said that dose sales in the three months to March 31, 2012, compared to the same period last year, grew in all regions.

The company said there was a 47 percent increase in the US, Asia Pacific was up 46 percent, and Europe increased eight percent.

Sirtex said it had reported 31 consecutive quarters of sales growth.

Mr Wong said that the company's long term global expansion strategy would ensure the continued growth of the business and the demand for the company's liver cancer therapy.

Sirtex was up 31 cents or 5.85 percent to $5.61.

NOVOGEN

Novogen subsidiary Marshall Edwards has received US Food and Drug Administration approval for clinical trials of ME-344 for cancer.

Novogen said that following FDA approval of the its investigational new drug application Marshall Edwards was in the process of initiating a phase I clinical trial of the intravenous mitochondrial inhibitor ME-344 in patients with solid refractory tumors.

Marshall Edwards chief executive officer Dr Daniel Gold said the approval was an "important milestone" and the company had advanced the two most promising oncology drug candidates into the clinic.

"As we near the completion of our phase I clinical trial of ME-143 and prepare for its next phase of development, we are excited to initiate our first human study of ME-344," Dr Gold said. "We believe ME-344 is a novel compound that has the potential to significantly improve treatment outcomes for patients with cancer, but first it is important to confirm its safety and tolerability in patients while establishing an optimal dose for future trials."

Novogen said the phase I trial of ME-344 was being conducted in collaboration with the Sarah Cannon Research Institute.

The company said that the open-label, dose-escalation trial would evaluate the safety and tolerability of intravenous ME-344 in patients with refractory solid tumors, as well as characterize its pharmacokinetic profile and describe any preliminary clinical anti-tumor activity observed.

Novogen said that patients would be administered intravenous infusions of ME-344 once weekly for three weeks and after safety assessment, could continue weekly dosing if a clinical benefit was determined.

The company said the trial was expected to enrol up to 24 patients at three sites.

Novogen fell two cents or 16.7 percent to 10 cents.

PRIMA BIOMED

Prima says the Canadian Patent Office has granted a patent entitled 'Mannose receptor bearing cell line and antigen composition' relating to its CVac ovarian cancer vaccine.
Prima said the patent would expire on September 29, 2018 and had been granted in Australia, Europe, and Japan.
The company said the granted patent claims were method of composition and protected the formulation of Prima's autologous dendritic cell vaccine CVac.
Prima said that CVac was composed of a patients' own dendritic cells pulsed with the cancer antigen Mucin-1, conjugated to oxidised mannan fusion protein.
The company said that pulsed dendritic cells were re-injected into the patient to stimulate an immune response to the Mucin-1 cancer antigen.
Prima was down one cent or 4.3 percent to 22.5 cents with 6.4 million shares traded.

BPH ENERGY, MOLECULAR DISCOVERY SYSTEMS

BPH Energy's Molecular Discovery Systems has been granted a US patent entitled 'Tumor Suppressor Factor' extended by 264 days and valid until August 2021.
BPH said that Molecular Discovery Systems (MDS) secured the rights to the tumor suppressor gene HLS5, both as a potential cancer therapeutic target and also underpinning its involvement in other diseases.
BPH said that HLS5 research had received high-priority funding and MDS would continue working with Western Australian Institute for Medical Research's Prof Peter Klinken and his research group to develop HLS5.
BPH was up 0.1 cents or 3.85 percent to 2.7 cents.

PHARMAXIS

UBS AG and related bodies corporate have become substantial shareholders in Pharmaxis with the acquisition of 15,307,015 shares or 5.00 percent.
The Hong Kong-filed initial substantial shareholder notice said the London UK and Sydney Australia branches were fund managers, beneficial owners and acting as prime brokers in relation to the shares.
The notice named a range of nominee companies and said that parties to the prime brokerage agreement included the Zambezi Absolute Return Fund, National Australia Bank, Regal Funds Management Pty Ltd as trustee for Atlantic Absolute Return Fund.
Pharmaxis fell 2.5 cents or 1.9 percent to $1.32.

GENETIC TECHNOLOGIES

Founder Dr Mervyn Jacobson has reduced his substantial holding in Genetic Technologies from 150,200,800 shares (43.13%) to 136,473,684 shares (29.36%).
In the change of substantial shareholder notice Dr Jacobson said he most recently sold 10,528,318 shares on-market for $1,000,000 or 9.5 cents a share.
Dr Jacobson said he bought shares from the date of his last notice in March 2005 until May 17, 2006 and from May 19, 2011 until February 8, 2012 sold 3,931,900 shares in small parcels with many parcels worth $7,000 each.
Genetic Technologies fell 0.6 cents or 6.1 percent to 9.3 cents.

GENETIC TECHNOLOGIES

Chairman Mel Bridges has acquired an indirect interest in 500,000 Genetic Technologies shares (0.11%) for $47,833 or an average price of 9.7 cents a share.

The change of director's interest notice said Mr Bridges held the indirect interest as a controlling shareholder of Parma Corp.