Biotech Daily

Monday August 9, 2010

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: BONE UP 7%; BENITEC DOWN 10%**

*** VALE EASTLAND'S CALVIN ROSS**

*** EASTLAND RAISES $2.3m**

*** LIFESCAN, UNIVERSAL BIOSENSORS' ONETOUCH VERIO LAUNCH**

*** QRX GERMAN PHASE II COMPARATIVE STUDY BACKS IV MOXDUO**

*** YM PHASE I CYT387 SUCCESS EXPANDS TRIAL; KILLS PROGRAM**

*** CAPITAL GROUP CLIENTS REDUCE TO 8% OF COCHLEAR**

*** AVEXA APPOINTS 5th DIRECTOR IAIN KIRKWOOD, AWAITING REVIEW**

*** JAPAN GRANTS TISSUE THERAPIES' 3rd VITROGRO PATENT**

MARKET REPORT

The Australian stock market climbed 0.63 percent on Monday August 9, 2010 with the S&P ASX 200 up 28.8 points to 4594.9 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 13 fell, four traded unchanged and 10 were untraded.

Bone Medical was best, up half a cent or 7.1 percent to 7.5 cents with 38,560 shares traded, followed by Universal Biosensors up nine cents or 6.2 percent to $1.55, with 379,794 shares traded.

Cathrx and Tissue Therapies climbed more than five percent; Acrux, Biota, Cellestis, QRX and Virax rose more than two percent; with Alchemia, Cochlear, Nanosonics and Psivida up more than one percent.

Benitec led the falls, down 0.3 cents or 10 percent to 2.7 cents with 104,500 shares traded, followed by Patrys down 8.7 percent to 10.5 cents with 30,000 shares traded.

Novogen lost 6.7 percent; Antisense was down 5.9 percent; Living Cell and Phosphagenics fell more than four percent; Circadian, Prima and Viralytics shed two percent or more; with Heartware, Mesoblast, Pharmaxis and Resmed down more than one percent.

CALVIN ROSS: 2.2.1953 – 2.8.2010

I was deeply saddened to hear of the death of Eastland Medical Systems director and the co-inventor of its Artimist sublingual malaria treatment, Calvin Ross.
Mr Ross was in Melbourne on July 28 presenting the Artimist story.
He was passionate about the children, primarily in Africa, who were dying unnecessarily "every 30 seconds" from treatable malaria.
Mr Ross said that as a sub-lingual spray Artimist could save children's lives at far lower costs than the more difficult to administer intra-venous quinine.
While many biotechnology company directors and executives display concern for their target patients, I was a little taken aback at Mr Ross's deep concern for children with malaria and his determination to provide a viable alternative therapy.
We spoke at the Melbourne meeting and discovered mutual interests in aviation and vintage motorcycles and cars.
The news that Calvin had died, possibly from a deep vein thrombosis, on his return to England was a great shock and great loss for the industry.

David Langsam, Editor

EASTLAND MEDICAL SYSTEMS

Eastland has raised $2,277,000 through the placement of 56,925,000 shares at four cents a share.
Eastland said its Artimist program including a phase III trial later this year, was on-track.
Eastland was up half a cent or 10.9 percent to 5.1 cents with 2.2 million shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says Johnson & Johnson's Lifescan will launch its Onetouch Verio diabetes test in Australia on September 1, 2010.
Universal Biosensors chief executive officer Mark Morrisson told Biotech Daily that the launch of the device developed by his company in Australia was "a huge vote of confidence" by Johnson & Johnson, a company that had a strategy of being number one or at least number two in its target markets.
Mr Morrisson said the diabetes glucose test market in Australia was large and growing with an estimated one in seven Australians likely to develop type II diabetes.
Mr Morrission said that a World Health Organisation estimate said there were 941,000 diabetics in Australia in 2000, likely to grow to 1.7 million by 2030.
In its media release Universal Biosensors said Lifescan had a presence in 75 countries supporting its range of diabetes devices including blood glucose meters, test strips, lancets and lancing devices and diabetes management software.
Universal Biosensors said that to launch and support the Onetouch Verio product glucose meter in the Australian market, Lifescan had built a new organization comprising of sales, marketing, operations and customer service.
"Diabetes is a national health care priority and to have one of the world's greatest health care companies now available to support people living with diabetes in Australia, is phenomenal," Mr Morrisson said.
"It is exciting to see the launch of a blood glucose system that is made in Australia and also offers such accurate technology," Mr Morrisson said.
Mr Morrisson told Biotech Daily that people with type 2 diabetes needed an average of two tests a day, but people with type 1 diabetes could require eight tests a day.
Universal Biosensors manufactures the disposable test strips at its Melbourne facility.
Universal Biosensors was up nine cents or 6.2 percent to $1.55.

QRX PHARMA

QRX says its phase II comparative proof-of-concept study has shown that intravenous Moxduo compares favorablY to equivalent doses of intravenous morphine.

QRX said that for moderate to severe post-operative pain in patients following hip replacement surgery, its intravenous Moxduo with 0.5mg morphine and 0.5mg oxycodone provided greater pain relief with less drug and fewer side effects than morphine alone.

QRX chief executive officer Dr John Holaday told Biotech Daily that the trial was in two parts with an anaesthetist providing equal doses of Moxduo compared to 1.0mg morphine with better pain relief and in the second part of the trial patients self-administered the drugs through a push-button system in which patients using Moxduo averaged 13 button pushes compared to 17 button-pushes for morphine, for the equivalent pain relief.

Dr Holaday said in a media release to the ASX that the trial data was “yet another important milestone demonstrating the significant efficacy and improved safety of our Moxduo product portfolio across multiple dual opioid formulations”.

The 40-patient, randomized, double-blind, active-controlled, investigator study was conducted at Germany’s Cologne-Merheim Medical Center, University Hospital of the Witten Herdecke University and Cologne University Hospital.

The study had a 65-minute dose-titration phase in which fixed doses were given once every five minutes until a strong analgesic effect occurred; followed by a 47-hour patient-controlled phase in which patients could self administer up to once every six minutes.

Primary endpoints determined whether intravenous co-administration of morphine and oxycodone had fewer opioid-related adverse events than morphine alone at equi-analgesic doses; and whether the dual opioid provided a different analgesic response than morphine alone.

During the initial 65 minute period, the primary efficacy endpoint was the difference in the sum of pain intensity (SPID) scores from baseline for each patient. Over this period, SPID scores showed 50 percent better pain relief or analgesic efficacy among patients in the dual opioid study group compared to those receiving morphine alone.

QRX said that 67 percent of patients receiving the dual opioid reported good to excellent improvement compared to 53 percent of those receiving morphine alone.

During the entire 48 hour study period, SPID scores were 10 percent higher among patients in the dual opioid study group compared to those receiving morphine alone.

Patient-controlled data showed that the dual opioid group achieved better pain relief faster and with less drug with 13 doses of dual opioid compared to 17 doses of morphine.

The company said its intravenous dual opioid dosing was well tolerated, with nausea and vomiting being the most common adverse events.

QRX said 24 percent of dual opioid patients had mild nausea and five percent had moderate to severe nausea; compared to the morphine group with 53 percent having mild nausea and 11 percent experiencing moderate to severe nausea.

The company said that 10 percent of dual opioid patients experienced mild vomiting and none had severe vomiting compared to 16 percent of patients receiving morphine alone who experienced mild vomiting and 11 percent who had moderate to severe vomiting.

QRX said that none of the dual opioid patients experienced low blood oxygen levels compared to 16 percent of morphine alone patients having oxygen desaturation, indicating less risk of respiratory depression with intravenous dual opioid.

The company said the results were consistent with a growing body of data from five QRX clinical trials and five external investigator studies, demonstrating better pain control with at least a 50 percent reduction of significant opioid-induced adverse events.

QRX was up two cents or two percent to $1.00.

YM BIOSCIENCES (CYTOPIA)

YM Biosciences has completed dose-escalation in 21 patients with myelofibrosis in the initial part of its phase I/II clinical trial of CYT387 at Mayo Clinic.

YM acquired the compound with Cytopia earlier this year (BD: Jan 28, Feb 1, 2010).

YM said that there were no voluntary withdrawals reported and the CYT387 kinase enzyme JAK1 and JAK2 inhibitor showed “significant activity in reducing spleen size and controlling constitutional symptoms in these patients”.

The company said that 15 patients had been enrolled in the phase II portion of the study and given the favorable biological activity and safety data, YM said it intended to expand the program from 60 to 120 patients at up to six centers in the US, Canada and Australia, subject to regulatory approval.

YM said detailed safety and activity data for CYT387 was planned to be presented at the American Society of Hematology meeting in Orlando, Florida in December 2010.

YM said myelofibrosis was a chronic debilitating unmet medical need, in which a patient's bone marrow was replaced by scar tissue and for which treatment options were limited or unsatisfactory due to both efficacy and safety concerns.

The company said that dosing in the phase I dose-escalation trial began in November 2009 ranging from 100mg to 400mg daily for up to nine months.

YM said that reversible, dose-limiting toxicities were observed in two patients at the 400mg dose-level, primarily an asymptomatic grade 3 amylase and lipase elevation and a grade 3 headache with both patients subsequently resuming treatment with CYT387 at reduced doses.

The company said that the majority of patients experienced a rapid splenic response of a magnitude sufficient to encourage YM to increase the total number of 60 patients to a maximum of 120 patients, subject to regulatory approval.

YM said the trial expansion would allow exploration of the dose-dependency of the biological activity observed in the phase I portion of the study.

The company said the expansion would facilitate the collection of more safety and efficacy data at the two doses of interest (150mg and 300mg) while allowing detailed analyses of particular patient subsets.

YM said the initial protocol measured spleen size reduction by palpation, but magnetic resonance imaging was proposed to be included in the expanded protocol.

The chair of the study, Mayo Graduate School haematology professor Prof Ayalew Tefferi said the trial showed “very favorable biological activity data for CYT387, with disease-modifying effects comparable to other JAK2 inhibitors evident in my myelofibrosis patients, including significant spleen size reduction, improvement in constitutional symptoms and favorable haematological changes”.

“The lack of patient withdrawal from the study is also testament to the tolerability and patient acceptability of this drug,” Dr Tefferi said.

YM chief operating officer Dr Nick Glover said that the company was “on track to advance CYT387 towards an [new drug application]-enabling study as early as 2011 and is reviewing opportunities for the compound in the numerous other indications in which evidence of activity has been shown with this family of molecules”.

YM chief executive officer David Allen said the results had led to the termination of expenditure on its separate Aerolef program.

“We believe that CYT387 has the potential to be a competitive molecule across a spectrum of disorders, including indications in haematology, oncology and inflammatory diseases. As such, we are allocating our resources accordingly in order to maximize its preclinical and clinical development in the near term,” Mr Allen said.

YM is based in Canada and listed on the Nasdaq.

COCHLEAR

The US based Capital Group Companies has further reduced its substantial shareholding in Cochlear from 5,050,049 shares (8.93%) to 4,427,062 shares (7.83%).
Capital Group increased its holding in Cochlear to as much as to 7,322,475 shares (13.03%) on September 11, 2009, before beginning reductions in May (BD: May 11, 2010).
Capital Group said the 622,987 shares were sold at an average price of $70.93.
Cochlear climbed 99 cents or 1.4 percent to $71.28.

AVEXA

Avexa has appointed Iain Kirkwood as a non-executive director.
The company is awaiting a strategic review of its assets following the failure of apricitabine to show significant phase III trial benefits over 3TC for HIV (BD: Feb 4, Mar 23, 2010).
Avexa has been unable to find a major partner for apricitabine and has been considering options including a "regional" pharmaceutical company partnership as well as what to do with $23 million in cash (BD: May 10, 24; Jun 18; Jul 6, 2010).
Mr Kirkwood joins the chairman Joe Baini and directors Bruce Hewett, Steven Crowley and Bell Potter advisor, Jet Soerdirdja.
Avexa's largest shareholder with 16.1 percent of the company, Calzada, has requested board representation but has been rebuffed by the existing board.
Avexa said the appointment of Mr Kirkwood reaffirmed its "commitment to building a strong and dynamic team".
The company said Mr Kirkwood had "extensive operational, financial and general management experience, particularly in the life sciences industry".
Avexa said Mr Kirkwood was a director of Medical Developments International, Vision Group and Broadvector and was previously the chief financial officer of FH Faulding & Co and was once the chief executive officer of Epitan, now Clinuvel.
Most recently, Mr Kirkwood came to prominence acquiring Circadian's 12 percent of Metabolic on behalf of the Queensland-based Brazil Farming, run by Franklyn and Bobbie Brazil (BD: May 14, 2008).
In turn, David Franklyn's Entrust Funds Management acquired the Brazil holding through Adelaide plastic surgeon Dr Tony Moore (BD: Apr 20, 2009).
Metabolic was renamed Calzada with Mr Franklyn a the executive chairman and reformed the ownership of Polynovo, acquiring 100 percent of the company from Xceed Capital and the Commonwealth Scientific and Industrial Research Organisation (BD: Feb 19, 2010).
Avexa fell 0.1 cents or 3.3 percent to 2.9 cents.

TISSUE THERAPIES

Tissue Therapies says Japan has granted it the third in the family of core Vitrogro patents, 'Skin Regeneration System'.
Tissue Therapies said it had multiple Vitrogro patents granted in the US, South Korea, South Africa, Australia and New Zealand.
Tissue Therapies was up one cent or 5.3 percent to 20 cents.