Biotech Daily

Tuesday December 16, 2008

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECHS DOWN: VENTRACOR UP 22%, NEUREN DOWN 17%**

*** PEPLIN COMPLETES PHASE III SKIN CANCER TRIAL ENROLMENT**

*** FRANCE FUNDS AVITA'S 200-PATIENT RECELL TRIAL**

*** QRX BEGINS COMPARATIVE STUDY OF MOXDUOIR FOR PAIN**

*** $2.4m MILESTONE PAYMENT EASES ALCHEMIA'S CASH PAIN**

*** BIONOMICS OPTIONS TO RAISE $6.9m**

*** NEURODISCOVERY IN CASH PAIN OVER NSL-043**

*** SPACELABS TO DISTRIBUTE USCOM HEART MONITOR**

*** RESMED APPOINTS STEIN JACOBSEN EURO-COO**

MARKET REPORT

The Australian stock market shed 1.0 percent on Tuesday December 16, 2008 with the All Ordinaries down 36.8 points to 3,498.9 points.

Eight of the Biotech Daily Top 40 stocks were up, 15 fell, four traded unchanged and 13 were untraded.

Ventracor was best, up 0.9 cents or 21.95 percent to five cents with 2.6 million shares traded, followed by Alchemia up 19.05 percent to 12.5 cents with 2.0 million shares traded, Prana up 16.67 percent to 35 cents and Phylogica up 11.11 percent to four cents.

Biota climbed 6.06 percent; Bionomics was up five percent; Living Cell rose 4.55 percent; CSL climbed 3.2 percent; with Pharmaxis up 2.8 percent.

Neuren led the falls, down one cent or 16.67 percent to five cents with 96,400 shares traded, followed by Polartechnics down 8.33 percent to 16.5 cents and Circadian down 7.69 percent to 60 cents.

Starpharma lost 6.52 percent; Resmed was down 5.26 percent; both Arana and Avexa fell 4.76 percent; Cochlear and Heartware were down more than three percent; Acrux, Antisense, Benitec, Clinuvel, Mesoblast and Viralytics shed more than two percent; with Cellestis and universal Biosensors down more than one percent.

PEPLIN

Peplin has completed enrolment of 250 patients in its pivotal phase III US and Australian clinical trial of PEP005 Gel for non-head actinic keratosis.

Peplin said actinic or solar keratosis was a common pre-cancerous skin condition affecting between 40 and 60 percent of adult Australians and accounting for at least 5.8 million annual visits to the dermatologist in the US.

The company said the phase III Region-1 trial aims to replicate the safety and efficacy demonstrated in earlier studies of PEP005 (ingenol mebutate) Gel, for actinic keratosis lesions on non-head treatment areas, which include the trunk and extremities.

Peplin expects to announce the results of the Region-1 trial in the first half of 2009.

Peplin's chief executive officer Tom Wiggans said completion of enrolment for the first phase III trial was "a significant milestone in what has been an exciting phase for Peplin".

"The enthusiasm for the trial and the speed of enrolment emphasizes the unsatisfied medical need which our product addresses," Mr Wiggans said.

"We believe PEP005 Gel and its short course of therapy represents a significant advance in the treatment of this common skin condition, which if left untreated can progress to non-melanoma skin cancer," he said.

Peplin said Region-1 was a multi-center, randomized, double-blind, parallel group, vehicle-controlled clinical trial conducted at Australian and US sites under a special protocol assessment with the US Food and Drug Administration.

The company said the special protocol assessment showed the FDA's agreement that the design, clinical endpoints and planned statistical analyses of the trial protocol were adequate to form a basis for approval of a new drug application.

The primary efficacy endpoint for this clinical trial is the complete clearance rate of actinic keratosis lesions within the assigned treatment area. The secondary efficacy endpoint will be the partial clearance rate of actinic keratosis lesions within the treatment area.

Peplin will evaluate efficacy on the 57th day after treatment.

The company said that Region-1 was the first of the planned phase III trials for PEP005 Gel for actinic keratosis.

Pending supporting data from Peplin's dose-ranging phase IIb clinical trial of patients with actinic keratosis lesions on their head and a successful end-of-phase II meeting with the FDA, Peplin will begin a phase III trial for actinic keratosis lesions on the head in 2009.

Peplin was untraded at 28.5 cents.

AVITA MEDICAL

Avita says the French Ministry of Health is funding a 200 patient medico-economics study on the impact of Recell on burn wound healing.

Avita said that the first patients were enrolled and had been treated in the study which was part of a French program "to advance the implementation of innovative technologies".

The study is organized through the French government's Support to Innovative and Costly Technologies program as part of the government's effort to identify and introduce innovative, cost-effective technologies into routine medical care.

Twelve teaching and academic hospitals have been selected to participate in the study.

Avita said the primary goal was to demonstrate the medical effectiveness and economic benefits of the Recell technology to the hospital and health care system in the treatment of burns and wounds.

The safety and efficacy of Recell have been previously validated, the company said.

Avita said the program was "highly competitive" with 345 projects submitted for inclusion and only Recell and an artificial electronic heart, selected for participation and funding.

Avita chief executive officer Dr William Dolphin said the endorsement by French surgeons and the Ministry of Health was “a strong affirmation of the major medical benefits delivered by Recell to burn victims”.
Dr Dolphin said that all involved in the trial were “confident the economic benefits of the product will be clearly demonstrated in the results of the study as well.”
Avita said Pfizer has recently established a global regenerative medicine unit, Pfizer Regenerative Medicine along with initiatives for regenerative medicine from Johnson & Johnson, Glaxosmithkline, Roche, Novartis and other companies.
“Regenerative medicine is clearly the frontier of medical science,” Dr Dolphin said.
“The support by the French government and recent endorsement by key surgeons in the United Kingdom bodes well for the acceptance of Recell as the first commercially available bedside cell therapy and for its establishment as the standard of care for the treatment of burns, scar remodeling and other skin defects and injuries,” Dr Dolphin said.
Avita was up 0.1 cents or 2.63 percent to 3.9 cents.

QRX PHARMA
QRX Pharma will begin an efficacy and safety study of Moxduoir compared to equivalent doses of morphine and oxycodone alone for acute moderate to severe pain.
QRX said data from the study would be used to support final phase 3 trials required for a new drug application to the US Food and Drug Administration.
The company said it expected to complete dosing by April 2009.
QRX chief executive officer Dr John Holaday said clinical trials had shown the potential of Moxduo to provide equal or better analgesia with a reduction of total opioid dose and improved tolerability.
“This study is designed to provide direct evidence of enhanced efficacy when compared to equivalent analgesic doses of morphine and oxycodone alone,” said Dr Holaday said.
“Our goal is to demonstrate the clinical value and superiority of Moxduoir over its individual components in post-surgical acute pain relief,” Dr Holaday said.
QRX said the double-blind, randomized and repeated fixed-dose study would compare Moxduoir’s efficacy and safety to corresponding doses of oxycodone and morphine in patients experiencing moderate to severe pain following a scheduled bunionectomy.
The study is targeted to enroll 180 patients at six US clinical research sites.
The primary endpoints for this study are pain relief and intensity scores of Moxduoir versus equivalent doses of morphine and oxycodone alone during the first 24 hours following surgery.
Secondary endpoints include efficacy relating to the time to onset of analgesia and global assessment of effect and safety as measured by the incidence and intensity of opioid-related adverse events.
QRX said Moxduoir was a combination of morphine and oxycodone clinically shown to provide synergistic effects on pain relief, resulting in a significant reduction of total opioid dose and side effects.
Based on the company’s July 2008 meeting with the FDA, final phase III studies for Moxduoir would include a combination rule trial in patients experiencing post-surgery (bunionectomy) pain. Data collected from this comparative study would be used to select the optimal dose regimen and sample sizes for the combination rule trial.
QRX said no additional pharmacology, toxicology or long-term clinical safety studies would be required for regulatory submission and market approval.
QRX fell two cents or eight percent to 23 cents.

ALCHEMIA

Alchemia says it will receive $US1,625,000 ($A2,400,000) in milestone payments from its manufacturing and marketing partner, Dr Reddy's.

Alchemia said the "significant milestone towards the commercialization of its lead product, generic fondaparinux" was confidential under the agreement.

Alchemia chief executive officer Dr Pete Smith told Biotech Daily the key steps for the company's synthetic heparin (fondaparinux, marketed as Arixtra) were generating data on the stability of the active pharmaceutical ingredient, filing the drug master file and the submission of the abbreviated new drug application to the US Food and Drug Administration.

Alchemia said a $US1 million payment would be received in December 2008 and a further $US625,000 on the earlier of the approval of the abbreviated new drug application to FDA or December 31, 2009.

The company said the confidential trigger for the milestone payment signaled "important progress toward the filing of the fondaparinux abbreviated new drug application with the FDA".

Alchemia said that US sales of Arixtra (fondaparinux) in the 12 months to September 2008 were $US172 million, up 67 percent on the corresponding period last year.

The receipt of these payments further improves Alchemia's cash position, providing more than two years operational funding at current expenditure levels, the company said.

Alchemia was up two cents or 19.05 percent to 12.5 cents.

BIONOMICS

Bionomics says it expects to raise $6,937,714 from the exercise of 31,535,063 listed options at 22 cents each.

Bionomics said institutional and other shareholders had committed to exercise up to 15,000,000 of the BNOOB options at 22 cents, which expire on January 31, 2009.

The company said that the listed options were free attaching options to a capital raising in July 2005.

Bionomics said Phillip Capital would manage the underwriting of the exercise of the options and the final underwritten amount would be announced in January 2009.

The company said it had achieved major milestones in 2008 and had clinical trial and partnership prospects for 2009.

Bionomics said that it expected to complete its phase I trial of BNC105, report results and progress to a phase II clinical trial in 2009 as well as achieve a second major partnership.

Bionomics chairman Dr Peter Jonson said the funding would "take the company forward, continuing the development of BNC105 and securing a major deal, which are our significant objectives for 2009".

"We are pleased with the early show of support over six weeks before the expiry of BNOOB options, including an investment by a specialist life science investment fund," Dr Jonson said.

Phillip Capital and Intersuisse will receive fees in respect of the issue.

Bionomics was up one cent or five percent to 21 cents.

NEURODISCOVERY

Neurodiscovery will postpone the next clinical trial of NSL-043 for neuropathic pain until additional finance for the program can be secured.
The company said unless it can raise funds for its share of the research collaboration with Japan's Sosei Co it would have its ownership of the intellectual property and future revenues reduced.
Neurodiscovery said it had completed two positive phase I trial results, in addition to recently announced further pivotal pre-clinical efficacy data for NSL-043.
The company said on-going financing discussions with parties in Australia, Europe and Japan have not yet been successfully concluded.
As a result of funding issues and the need to preserve the company's cash reserves Neurodiscovery has told its joint development partner, Sosei Co, that "at this time, the company is unable to contribute to its share of the outstanding costs of development of NSL-043 for the period January to September 2008".
Neurodiscovery said that under the collaboration agreement with Sosei if it was unable to contribute to costs of development then Neurosolutions share of the ownership of the intellectual property and its right to receive 50 percent of the revenue would be reduced after taking into account the total costs contributed at the time the first revenue was received, unless otherwise agreed by the management committee of NSL-043.
The company said Neurosolutions had six months from the date of serving notice to raise additional funds to enable it to contribute to its outstanding payments and contribute to its 50 percent share of the costs.
Neurosolutions plans to meet with Sosei during December 2008 to discuss the strategy to progress and fund the development of NSL-043 into the next clinical trial.
The company said the potential dilution would be discussed.
Neurodiscovery was untraded at five cents.

USCOM

Uscom says the Spacelabs Healthcare will have exclusive distribution of its ultrasonic cardiac output monitor in the Americas, Europe, Middle East, Africa and India.
Uscom said Spacelabs was a Washington State-based developer, manufacturer and distributor of medical equipment and services.
The company said its Uscom 1A monitor offered "real-time, beat-to-beat measurements of 20 parameters of cardiovascular function including cardiac output, stroke volume and systemic vascular resistance with additional parameters such as cardiac power, stroke work and oxygen delivery".
Spacelabs' president of North America operations Joseph Davin said the monitor was "a logical complement to our comprehensive patient monitoring and diagnostic cardiology product offerings".
Uscom chief executive officer Paul Butler said Spacelabs distribution would increase delivery of the technology to the global market and "further realize our ambition of providing improved care at lower cost and reduced risk".
Uscom was unchanged at 25 cents.

RESMED

Resmed says Stein Jacobsen will replace Lasse Beijer as its chief operating officer in Europe from January 1, 2009.

Mr Beijer will continue to be employed as a non-executive senior advisor to the chief operating officer in Europe, until September 30, 2009.

Resmed said Mr Beijer would continue to receive his current salary, bonus and benefits until June 30, 2009.

The company said that from July 1, 2009 to September 30, 2009, Mr Beijer's base compensation will be at an annualized rate of 250,000 Swiss francs ($A323,000) and he will not be eligible for a bonus, but his other benefits will continue at their current rate.

From January 1, 2009 Mr Jacobsen will be the chief operating officer and continue in his current role as senior vice president of ventilation.

Resmed said Mr Jacobsen had been in the respiratory business for more than 20 years.

He joined Resmed in 2005 as chief operating officer for the Nordic region, after the acquisition of Polarmed Holding AS, a medical equipment distributor in the Scandinavian respiratory market, which Mr Jacobsen founded and led since 1993.

Mr. Jacobsen was served as chief operating officer of the Nordic region until July 2007, when he became senior vice-president of ventilation.

Mr Jacobsen will receive a base salary of 2,000,000 Norwegian kroner ($A435,000) and will be eligible for a bonus with a target of 70 percent of his base salary.

He will also be eligible to receive customary executive benefits, including an automobile allowance, health benefits and pension contribution.

Resmed fell 29 cents or 5.26 percent to $5.22.