Biotech Daily

Friday September 9, 2011

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ALCHEMIA UP 15%; LBT DOWN 11.5%**

*** ALCHEMIA STARTS PHASE II HYACT SMALL CELL LUNG CANCER TRIAL**

*** NOVOGEN'S MARSHALL EDWARDS BEGINS ME-143 SOLID TUMOR TRIAL**

*** UNIVERSAL BIO, SIEMENS $3m+ COAGULATION TEST COLLABORATION**

*** HEALTHLINX PARTNERS WITH CHINA'S CYTOGENDX FOR OVPLEX STUDY**

*** BPH'S CORTICAL DYNAMICS VALIDATES EQUIPMENT**

*** MEDICAL DEVELOPMENTS 15m SHARE CEO INCENTIVE PLAN**

*** FLUOROTECHNICS RAISES $615k TO GO EXPLORING**

*** PELA RESOURCES BRING NEW SUBSTANTIAL HOLDERS TO PHARMAUST**

*** JASON PETERSON INCREASES, DILUTED TO 6% OF ACUVAX**

MARKET REPORT

The Australian stock market climbed 0.16 percent on Friday September 9, 2011 with the S&P ASX200 up 6.7 points to 4,194.7 points. Seventeen of the Biotech Daily Top 40 stocks were up, 10 fell, nine traded unchanged and four were untraded. All Big Caps fell.

Alchemia was the best, up 5.5 cents or 14.9 percent to 42.5 cents with 801,590 shares traded, followed by Viralytics up 13 percent to 61 cents with 220,926 shares traded, Antisense up 12.5 percent to 0.9 cents with 6.1 million shares traded and Universal Biosensors up 11.1 percent to $1.00 with 827,146 shares traded.

Nanosonics climbed 8.55 percent; Bionomics and Genetic Technologies were up more than four percent; Prana was up 3.2 percent; Prima rose 2.5 percent; with Anteo, Compumedics and Psivida up more than one percent.

LBT led the falls, down 0.6 cents or 11.5 percent to 4.6 cents, with 115,300 shares traded.

Cellmid and Impedimed lost more than five percent; Allied Health and Optiscan fell four percent or more; Living Cell and Sirtex were down more than three percent; with Cochlear down 1.6 percent.

ALCHEMIA

Alchemia has dosed the first two of 40-patients in its phase II trial of hyaluronic acid irinotecan in small cell lung cancer.

Alchemia said the investigator-sponsored trial of hyaluronic acid irinotecan also known as hyaluronan irinotecan or HA-irinotecan was being conducted at Monash Cancer Centre, Southern Health and Peninsula Oncology Centre, Victoria.

The company said the study would examine the effectiveness of HA-irinotecan using its Hyact technology to target the anti-cancer drug irinotecan to the tumor.

In a teleconference, Alchemia's chief scientific officer Prof Tracey Brown said that the Hyact technology "improved currently used cancer drugs by targeting the CD44 protein".

"We get more drug into the cancer cells and it stays there longer, with up to 1000 times as much drug into the cancer cell," Prof Brown said.

Prof Brown said the cancer stem cells also expressed the CD44 protein and hyaluronic acid irinotecan would also target the stem cells, believed to be the source of resistance to cancer drug treatments.

Prof Brown said that patients with small cell lung cancer had limited treatment options and the trial would compare the safety and efficacy of HA-irinotecan or irinotecan.

Alchemia chief executive officer Dr Pete Smith said the trial would also investigate secondary markers of circulating tumor cells and cancer stem cells.

Dr Smith said the cost of trial would be paid primarily by Monash Cancer Centre, with Alchemia covering the costs of the drug, data analysis and monitoring.

Alchemia chief financial officer Charles Walker said the cost of the 18 month phase II small cell lung cancer trial was less than $400,000 compared to the $20 million for the 390-patient US Food and Drug Administration and European Medicines Agency directed phase III metastatic colorectal cancer trial due to begin this year (BD: Jul 12, 2010).

Dr Smith said that apart from revenues expected from the sales of Fondaparinux expected to assist fund the phase III trial there would be a need for further funding to provide working capital.

Dr Smith said a range of options had been considered and did not disclose how much the company hoped to raise.

Monash Cancer Centre oncologist Dr Vinod Ganju said that "based on the previous experience with HA-irinotecan in colorectal cancer, we hope to see improved patient outcomes in this trial".

"It is also interesting from a scientific point of view being the first trial to directly examine the impact of a therapy on lung cancer stem cells," Dr Ganju said.

Alchemia said that data presented at the American Association of Cancer Research last year showed that drugs formulated using its Hyact platform showed up to a 40-fold increase in potency against cancer stem cell populations (BD: Apr 21, 2010).

The company said the phase II trial would quantify cancer stem cells in biopsies of tumor tissue obtained from patients at the start, during and at the end of treatment.

"We are anticipating valuable insights into the mechanism of action of the platform as well as providing further data on the improved effectiveness of HA-irinotecan in another cancer," Prof Brown said.

Alchemia said that in a previous phase II study in colorectal cancer, HA-irinotecan more than doubled the time it took patients' tumors to progress compared to unformulated irinotecan.

The company said that up to 20 percent of the 220,000 new cases of lung cancer in the US were small cell lung cancer, which was aggressive with median survival from diagnosis of two to four months without treatment and five year survival of five percent.

Alchemia was up 5.5 cents or 14.9 percent to 42.5 cents.

NOVOGEN

Novogen's 65 percent subsidiary Marshall Edwards has begun a 24-patient phase I trial of lead drug candidate ME-143 in patients with refractory solid tumors.

Novogen said the trial was being conducted in collaboration with the Sarah Cannon Research Institute in Nashville, Tennessee, following the approval of an investigational new drug application by the US Food and Drug Administration.

The company said the phase I dose-escalation trial would evaluate the safety and tolerability of intravenous ME-143 in patients with refractory solid tumors.

Novogen said the trial was designed to characterize the pharmacokinetic profile of intravenous ME-143 and describe any preliminary clinical anti-tumor activity observed, with final data collected by July 2012.

Marshall Edwards chief medical officer Dr Robert Mass said ME-143 was "a promising drug candidate that has demonstrated anti-tumor activity in pre-clinical studies".

"Together with the Sarah Cannon Research Institute, we will be obtaining important information regarding dosing, safety and potential efficacy of intravenous ME-143 over the next several months, which will inform the design of our randomized phase II clinical trials in combination with standard-of-care chemotherapy," Dr Mass said.

Novogen said the trial was entitled 'Phase I Open Label Multicenter Dose Escalation Study of the Safety and Pharmacokinetics of ME-143 in Patients with Refractory Solid Tumors' with enrolment criteria and site information available at www.clinicaltrials.gov.

Novogen was up half a cent or 3.1 percent to 16.5 cents.

UNIVERSAL BIOSENSORS

Universal Biosensors says it will collaborate with Siemens Healthcare Diagnostics to development and commercialize point-of-care coagulation tests.

Universal Biosensors said it would develop a range of test strip and reader products, with the first test to be a modified version of its blood-clotting prothrombin time and international normalized ratio (PT/INR) test.

The company said it would "leverage its manufacturing expertise and resources" to manufacture and supply the developed test strips to Siemens.

Universal Biosensors said Siemens was one of the world's largest suppliers to the healthcare industry and a leader in the haemostasis market and would register, market and sell the developed products globally.

The company said the global market for point-of-care testing products was about $15 billion a year, with point-of-care coagulation testing products worth more than $750 million.

Universal Biosensors said it would receive an initial technology access fee of $US3 million, with six payments on achievement of milestones relating to feasibility, regulatory submissions and launch of the products to be developed.

The company said that as products were commercialized it would generate revenues from each strip manufactured, on pre-agreed, confidential terms.

Universal Biosensors chief executive officer Paul Wright said the deal was "an important and exciting step forward".

"It validates our technology and capabilities outside the field of diabetes care, establishes a further partnership with a global healthcare leader and creates an exciting framework for future earnings from our technology," Mr Wright said.

Universal Biosensors said the partnership did not cover patient self-testing which was a further opportunity to exploit its PT/INR testing technology.

Universal Biosensors climbed as much as 18 cents of 20 percent to $1.08, before closing up 10 cents or 11.1 percent at $1.00.

HEALTHLINX

Healthlinx says it has research agreements with China's Cytogendx Co for a 350-patient academic study as the first step to launch the Ovplex ovarian cancer diagnostic in China.
Healthlinx said the study would be conducted by principal investigator of Wuxi Maternal and Children's Hospital's Dr Fei Xu to validate Ovplex in the Chinese population.
The company said that with a successful result, the parties would proceed with a State Food and Drug Administration approval pathway to have Ovplex registered for sale.
Healthlinx said the two companies would co-fund the study which would take nine to 12 months to complete and was seen as the precursor for State Food and Drug Administration (SFDA) approvals.
Healthlinx managing director Nick Gatsios said that China was "potentially a huge market for Ovplex, so the commencement of the study is excellent news for the company and its shareholders".
"Cytogendx is a highly respected healthcare company in the Chinese market working with groups to conduct clinical trials and then proceeding with SFDA approvals and distribution of products throughout China," Mr Gatsios said.
Healthlinx said 2011 was "a highly successful year … in Asia with over-budget sales of Ovplex in Singapore, excellent progress made with the ongoing 220-patient … study in South Korea, signing a commercial distribution deal with SCL for South Korea and the pending launch of Ovplex in other South East Asian countries.
Healthlinx was up half a cent or 26.3 percent to 2.4 cents with 13.8 million shares traded.

BPH ENERGY, CORTICAL DYNAMICS

BPH Energy says its 3.6 percent subsidiary Cortical Dynamics has validated the major components of the brain anaesthesia response (BAR) monitoring system.
Cortical Dynamics is hoping to list on the ASX following an initial public offer at the end of this month (BD: Aug 16, 2011).
BPH said the aim of the study was to verify the performance of the BAR system by evaluating the performance of all the signal gathering and analyzing components.
The company said the study replicated and extended results regarding the effect of the hypnotic agent benzodiazepine alprazolam on brain electrical activity measured by electroencephalogram (EEG) in healthy subjects.
BPH said that 10 healthy participants between the ages of 18 and 40 ingested a single 1mg oral dose of alprazolam after a baseline EEG recording was taken.
The company said the EEG was recorded and analyzed by employing two of the three components of the complete BAR system, the data acquisition module which amplified and analyzed the EEG and Cortical's adhesive scalp electrodes, with subjects EEG recorded every hour for a period of three hours.
BPH said the study demonstrated that the major components of the system were capable of robustly replicating the well known pharmaco-EEG phenomena of benzodiazepine agents, the benzodiazepine-induced beta-buzz.
The company said the replication of the phenomenon indicated that the hardware and software components were functioning correctly.
BPH said the study concluded that the physiologically-inspired approach of the BAR monitoring system was capable of detecting the effects of the hypnotic agent alprazolam.
The company said the BAR system measured brain electrical activity to indicate how deeply anaesthetised a patient was during an operation and was designed to assist anaesthetists and intensive care staff in ensuring patients do not wake up un-expectedly.
BPH was up 0.3 cents or 10.7 percent to 3.1 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says chief executive officer John Sharman will be entitled to buy more than 1.5 million shares at discounts ranging from 49 to 83 percent.
Medical Developments said Mr Sharman's long term incentive plan would "encourage his long term commitment to the business".
The plan entitles Mr Sharman to buy up to three percent of the issued capital of the company at 25 cents a share, in one percent tranches on reaching three specified milestones.
The company said that at least 60 percent of shares purchased would be escrowed for 12 months.
Medical Developments said that the first of Mr Sharman's milestones was maintaining a market capitalization of $25 million (49 cents per share) for more than three months.
ASX data says that at the close of business yesterday the company was trading at 47 cents with a market capitalization of $21 million.
Medical Developments full year accounts said the company had 51,357,651 shares on issue at June 30, 2011.
Mr Sharman would be allowed to acquire about 513,576 shares in each tranche, increasing with any new share issue.
In his last director's interest notice chairman David William said he held 26,519,321 shares.
The company said the second milestone was a market capitalization of $50 million, with a share price of 97 cents for more than three months, with the third milestone a market capitalization of $75 million with a share price of $1.46 for more than three months.
Medical Developments said Mr Sharman could elect to receive a cash bonus, the after-tax amount of which must be used in its entirety to purchase shares and where this election was exercised, the number of shares purchased would be reduced.
The company said the announcement was an incomplete summary of the long term incentive plan, with the details in the annual report.
Medical Developments fell one cent or 2.1 percent to 46 cents.

FLUOROTECHNICS

Fluorotechnics has raised $615,000 through the issue of convertible notes at $1.00 a note to fund its "focus on the resources sector" (BD: Jun 22, 2011)
The notes were issued with no interest and convertible within two years.
Fluorotechnics was untraded at two cents.

PHARMAUST

Three initial substantial shareholder notices have been filed with each acquiring 37,500,000 shares or 8.03 percent of Pharmaust.
The notices said the shares were issued as consideration for the acquisition of Pela resources.
The notices were filed in the names of Gregory Cunnold and Lara Groves as trustees for the Stratford Trust of 21 Stratford Street east Fremantle, Western Australia; Newco of 63 Moray Avenue, Floreat, Western Australia signed by Gary Elwell; and Trevor John as Trustee for Planet Nominees of 34b Planet Street, Carlisle, Western Australia.
Pharmaust was up 0.3 cents or 15 percent to 2.3 cents.

ACUVAX

Jason Peterson has increased his substantial holding in Acuvax but has been diluted through a placement.

The change of substantial shareholder notice said Mr Peterson increased and was diluted from 99,000,000 shares (10.6%) to 152,000,000 shares (6.2%).

Acuvax was unchanged at 0.2 cents with 1,000,000 shares traded