Biotech Daily

Tuesday July 29, 2008

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECHS DOWN: NOVOGEN UP 5.5%, CHEMGENEX DOWN 7%**

*** AVANTOGEN PLACEMENT TO INCREASE IN HAWAII BIOTECH**

*** ORPHAN-DRUG DESIGNATION CLINUVEL'S 1ST US FDA APPROVAL**

*** MEDIGAS ITALIA TAKES 2.74% STAKE IN COMPUMEDICS**

*** COGSTATE IN US PARTNERSHIP; RAISES $1.4m**

*** LIVING CELL APPOINTS DR ROBERT CASPARI CEO**

*** AVEXA REDUCES CASH BURN**

*** CYTOPIA APPOINTS PROF AYALEW TEFFERI JAK2 TRIAL CHAIR**

*** PORTLAND APPOINTS RALPH STONELL CFO**

*** NEUREN REQUESTS CAPITAL RAISING TRADING HALT**

MARKET REPORT

The Australian All Ordinaries Index fell 1.3 percent on Tuesday July 29, 2008, losing 66.6 points to 4,923.3 points.

Five of the Biotech Daily Top 40 stocks were up, 15 fell, 12 traded unchanged and eight were untraded.

Novogen was best, up six cents or 5.5 percent to $1.15 on small volumes, followed by Living Cell up 5.41 percent to 19.5 cents.

Mesoblast climbed 4.76 percent; with Phylogica and Prana up more than one percent.

Chemgenex led the falls, down eight cents or 7.41 percent to $1.00 on small volumes, followed by Psivida down seven percent to $2.79.

Cellestis and Viralytics lost more than five percent; Circadian and Cytopia fell more than four percent; Alchemia, Benitec and Pharmaxis were down more than three percent; Acrux, Avexa, Peplin and Resmed shed more than two percent; with Cochlear and Starpharma down more than one percent.

AVANTOGEN

Avantogen chief executive officer Dr William Ardrey says his company expects to make a significant placement to brokers BBY to fund an increased stake in Hawaii Biotech.

Dr Ardrey spoke at an investors and media briefing organized by Monsoon Communication in Melbourne and said that Avantogen had a pipeline of preclinical and clinical drugs with related companies Avantogen Inc and Hawaii Biotech.

Dr Ardrey said that Avantogen owned 33 percent of Hawaii Biotech and the capital raising with BBY (formerly Burdett Buckeridge Young) was intended to raise funds to acquire more stock in the company that has begun a phase I trial for West Nile Fever and expects to begin a phase I trial in Dengue fever patients in November 2008.

Dr Ardrey said he would like Avantogen to eventually own about 70 percent of Hawaii Biotech.

He said that he expected Novembe, December and January to be “very interesting” for Avantogen.

He told the meeting that Australian biotechnology companies seemed focused on taking drugs from discovery to registration, but his intention was to licence or partner the drugs at the end of phase I so that large pharmaceutical companies could carry the cost of phase II and III trials.

Dr Ardrey said Avantogen was using recombinant DNA to create vaccines and it was a protein-based platform technology.

He said the platform technology was approved by the US Food and Drug Administration and supported by the Pediatric Dengue Vaccine Initiative which in turn was funded by the Bill and Melinda Gates Foundation.

Dr Ardrey said the West Nile Fever trial had dosed 18 of its 24 patients and that a phase IIb trial of RP101 for pancreatic cancer had treated 47 patients of the targeted 100-120 patients.

He said that apart from vaccines, the company was also developing tests for viruses.

“If you can make the vaccine, you can make a test kit for the disease,” Dr Ardrey said.

He said that there had been a great deal of merger and acquisition business with large pharmaceutical companies particularly interested in vaccine development.

Dr Ardrey said West Nile Fever was virtually unknown in Australia, but was “a major issue in the US”.

He said Dengue fever was established in Queensland, where Avantogen has its headquarters.

Dr Ardrey said a vaccine for seasonal and pandemic influenza would begin clinical trials in February 2009 using the recombinant vaccine platform.

“We own 95 percent of the patent,” he said, explaining that Glaxosmithkline held the remaining five percent.

Dr Ardrey said RP101 was being trialed for pancreatic cancer and was licenced to Sciclone Pharmaceuticals. He said Avantogen had received $4 million from the deal with a further $1 million due when the drug met regulatory hurdles.

He said the company had revised its board and had appointed investment banker Pat Elliott as chairman and Gardasil inventor Prof Ian Frazer had been appointed as a scientific adviser to Hawaii Biotech.

Dr Ardrey said that Dr Richard Opara and his related company Chopin One held about 75 percent of Avantogen.

On April 8, 2008 Dr Opara reduced his direct and indirect holdings from 86.26 percent to 77.89 percent (see Biotech Daily April 28, 2008).

Dr Ardrey said he expected the placement to BBY to be at five cents a share.

Avantogen was untraded at 7.5 cents.

CLINUVEL

The US Food and Drug Administration has granted Clinuvel an orphan drug designation for its photo-protective drug, afamelanotide (CUV1647).
Clinuvel's chief executive officer Dr Philippe Wolgen said it was the first time the company had obtained regulatory approval in the US.
"This year the company has received recognition for its ground breaking approach to light related skin disorders from Europe and now the US," Dr Wolgen said.
Clinuvel said the orphan designation was for the treatment of erythropoietic porphyrias, which it said were "rare genetic diseases with no effective therapy for the phototoxic skin reactions caused by exposure to [ultra-violet] and sunlight.
To date sufferers have only been able to avoid sun and light and follow a restricted lifestyle, keeping indoors and covering up when venturing out in daylight.
Clinuvel said the decision recognized the properties of afamelanotide which stimulates production of the skin's natural photo-protective melanin.
The FDA's orphan drug designation is reserved for new drugs or therapies being developed to treat rare diseases or conditions that affect smaller populations in the US.
Erythropoietic porphyrias affect less than 200,000 people in the United States.
Commercially, afamelanotide will be a "first in class" drug entitling Clinuvel to market exclusivity in the US for seven years.
The orphan-drug designation also allows for an accelerated review process by the FDA.
Clinuvel said the next step in the regulatory process would be an investigational new drug for afamelanotide which was expected by the end of 2008.
Clinuvel said it was developing afamelanotide as a preventative treatment for a range of ultra-violet light-related skin disorders as well as cancer related treatments.
Trials are underway in five medical indications including erythropoietic porphyrias.
Clinuvel was unchanged at 32 cents.

COMPUMEDICS

Compumedics says Medigas Italia SrL, has joined Compumedics' share register with a strategic stake of 2.74 percent of the company.
Compumedics said Medigas was one of its European distributors for diagnostics equipment and the first distributor for its Somnilink sleep-treatment system and would have a full sleep diagnosis and treatment suite of products.
Medigas Italia is a member of the SIAD group of companies which is 34 percent owned by Praxair, a conglomerate listed on the New York Stock Exchange with $US9.4 billion of sales in 2007, of which 11 percent were generated from its healthcare division, which includes sleep apnoea treatment products.
Medigas Italia is a significant distributor of sleep diagnostics and sleep treatment products in Italy and the former eastern block countries, now including 13 countries where the SIAD group has its operations and facilities outside Italy.
Compumedics said it had completed a letter of intent with Medigas for the distribution of the Somnilink systems in June 2007.
Medigas has the third largest shareholding in the company.
Medigas sales and marketing director Giancarlo Fontana said the Compumedics' system "lifts treatment possibilities for sleep apnoea sufferers to a new level with its inherent capability for improving sleep efficiency".
"There are no rival products in this field and Medigas is pleased to have access to this new product," Mr Fontana said.
Compumedics was untraded at 18.5 cents.

COGSTATE

Cogstate says it has a strategic partnership with the Maryland-based United Biosource Corp to increase the market for cognitive testing in clinical trials.
Cogstate said pharmaceutical and life sciences company customers would be able to acquire both Cogstate's scientific and software capabilities with United Biosource's global operations to support full scale clinical development programs.
Cogstate said cognitive impairment was a defining aspect of many psychiatric and neurological diseases including Alzheimer's disease, schizophrenia, Parkinson's disease, attention deficit hyperactivity disorder (ADHD), depression and stroke .
United Biosource and Cogstate will provide "an integrated cognitive testing solution for use in phase I through IV clinical trials internationally".
Cogstate's chief executive officer Brad O'Connor said United Biosource "a perfect fit" with its portfolio of evidence-based cognitive testing capabilities.
The company said United Biosource's ratings services group was focused on standardizing the administration and scoring of clinically subjective outcome measures used as pivotal endpoints in clinical trials.
Cogstate said it had raised $799,000 in a private placement and $613,000 in a non-renounceable share rights issue.
Cogstate was untraded at 11 cents.

LIVING CELL TECHNOLOGIES

Living Cell director Dr Robert Caspari will replace chief executive officer Dr Paul Tan who continues as chief operating officer and head of New Zealand operations.
Living Cell said Dr Caspari was previously senior vice-president of commercial operations of Myogen Inc, vice-president and general manager for biopharmaceuticals at Novo Nordisk Pharmaceuticals and vice-president of medical and clinical affairs of Baxter International.
He has held senior executive positions with Somatogen, Boehringer Mannheim, Schering-Plough, Lederle Laboratories and Aurogen.
Living Cell said Dr Caspari was based in Boulder, Colorado.
The company has its American depository receipts on the international over the counter exchange (OTCQX) with the Bank of New York Mellon as its principal American liaison.
Living Cell said it had also started work with the Barbara Davis Center for Diabetes in Denver, Colorado towards conducting a clinical trial there in 2009.
Dr Tan will remain the chief executive officer of Living Cell New Zealand.
Dr Tan said the company was expanding its facilities and operations in New Zealand to meet the demand for Diabecell in clinical trials for 2009 onwards.
Living Cell climbed one cent or 5.41 percent to 19.5 cents.

AVEXA

Avexa's says its cash balance is four times its last quarter cash burn.
In its Appendix 4C cash flow document reported to the ASX for the three months to June 30, 2008 Avexa said its total operating and investing cash burn was $10,062,000 with $43,411,000 in cash holdings at the end of the month.
On June 27, 2008 Avexa told Biotech Daily the previous quarter's cash burn of $19,225,000 was extraordinary and included "significant start-up costs associated with its phase III HIV trials" and would not be repeated.
Avexa fell one cent or 2.94 percent to 33 cents.

CYTOPIA

Cytopia has appointed Prof Ayalew Tefferi as clinical study chair for its phase I/II study in patients with myelofibrosis.

Prof Tefferi is the professor of medicine and haematology at the Mayo Clinic College of Medicine in Rochester, Minnesota.

Cytopia said Dr Tefferi was an "expert in the treatment of myeloproliferative disorders", had authored more than 500 research publications and given hundreds of invited lectures in haematology. He serves on the editorial boards of leading haematology journals.

Cytopia said myelofibrosis patients suffered a bone marrow disorder in which the marrow is replaced by fibrous scar tissue.

The company said patients in the study would be treated with its "novel orally available compound CYT387" which inhibits the mutant JAK2 enzyme to specifically treat haematological malignancies, including myelofibrosis.

Cytopia said many of these diseases could lead to life threatening conditions such as leukemia and there were no effective long term treatments.

Cytopia chief executive officer Andrew Macdonald said Dr Tefferi and the company's other clinical investigators would document the clinical benefits of using the JAK2 inhibitor to treat blood disorders.

The company said that following the completion of "very encouraging in-vivo studies" at Oregon Health and Science University early in the year, CYT387 had been undergoing rigorous investigational new drug-enabling toxicology studies.

Cytopia expects that an investigational new drug application will be lodged with the US Food and Drug Administration by the end of the year.

Cytopia said that the discovery of a specific single activating mutation in the JAK2 enzyme in myelo-proliferative disorders in 2005 focused attention on developing a therapy for these diseases through selective inhibition of JAK2.

The company said it was a world leader in JAK2 kinase chemistry and held a broad range of JAK2 related patents.

Cytopia fell one cent or 4.76 percent to 20 cents.

PORTLAND ORTHOPAEDICS

Portland Orthopaedics has appointed Ralph Stonell as chief financial officer effective immediately.

Portland said Mr Stonell held a Bachelor of Economics from Macquarie University and most recently was the CFO for Stella Travel Services.

Portland was untraded at 2.4 cents.

NEUREN

Neuren has requested a trading halt pending an announcement regarding a capital raising.

Trading will resume on July 31, 2008 or on an earlier announcement.

Neuren last traded at 12 cents.