Biotech Daily

Wednesday October 22, 2008

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECHS DOWN:**
SUNSHINE HEART UP 23%, GENETIC TECHNOLOGIES DOWN 16%

*** GRAHAME LEONARD UPSETS GENETIC TECHNOLOGIES SPILL BID**

*** EXCLUSIVE: DR MERVYN JACOBSON EXPLAINS THE SPILL**

*** ANADIS BIOGARD STUDY APPROVED FOR ADJUNCT TO HIV THERAPY**

*** NOVOGEN'S GLYCOTEX BEGINS BEVERLY HILLS WOUND TRIAL**

*** BENITEC WHITE KNIGHT DR CHRIS BREMNER INVESTS $2m MORE**

*** HEARTWARE MEETING BACKS MOVE; DIVIDES ON INCENTIVE PLAN**

*** MONASH UNIVERSITY BUYS EVADO'S TRIALS SYSTEM**

*** ELLEX'S SIMON LUSCOMBE REPLACES CEO KEVIN MCGUINNESS**

MARKET REPORT

The Australian stock market shed most of yesterday's gain on Wednesday October 22, 2008 with the All Ordinaries down 131.3 points or 3.1 percent to 4,120.1 points. Ten of the Biotech Daily Top 40 stocks were up, 17 fell, seven traded unchanged and six were untraded.

Sunshine Heart was best, up 1.3 cents or 22.81 percent to seven cents with 175,428 shares traded, followed by Heartware up 9.09 percent to 60 cents and Cellestis up 8.72 percent to $2.12.

Biota climbed 5.06 percent; Avexa and Resmed were up more that four percent; Alchemia, Antisense and Circadian rose more than two percent; with Acrux up 1.37 percent.

Genetic Technologies led the falls, down 0.9 cent or 16.36 percent to 4.6 cents, followed by Ventracor down 12 percent to 11 cents and Labtech down 10.71 percent to 12.5 cents.

Phylogica lost 8.82 percent; Mesoblast fell 7.37 percent; Chemgenex and Proteome were down more than six percent; Living Cell, Optiscan and Polartechnics shed five percent or more; Benitec fell 4.08 percent; CSL, Novogen and Starpharma lost three percent or more; Phosphagenics and Prana shed more than two percent; with Arana and Cochlear down more than one percent.

GENETIC TECHNOLOGIES

Dr Mervyn Jacobson's nominated director to replace most of the existing board of Genetic Technologies, Grahame Leonard, has withdrawn his consent for the nomination.

Mr Leonard told Biotech Daily that his agreement to stand for the board of Genetic Technologies was dependent on his conducting satisfactory due diligence (see Biotech Daily; September; 18, 19 and 22, 2008).

Mr Leonard is a lawyer and accountant and chairman of the consulting firm Readify and a former president of the Jewish Community Council of Victoria.

Mr Leonard told Biotech Daily today that he completed due diligence on the company.

"I have now withdrawn my candidacy," Mr Leonard said.

Asked if the two events were connected, Mr Leonard said: "No comment."

The Corporations Act requires that a public company must have at least three directors.

Genetic Technologies' company secretary Tom Howitt told Biotech Daily that he understood that it was "too late for a replacement director to be nominated for the coming annual general meeting".

Dr Jacobson's resolution calls for the removal of chairman Henry Bosch, chief executive officer Michael Ohanessian and directors John Dawkins, David Carruthers and Dr Leanne Rowe. If passed, the resolution would leave Genetic Technologies with Dr Jacobson and Fred Bart as directors. Should Mr Bart continue, a third director would be required.

Exclusive: Dr Mervyn Jacobson responds

Dr Jacobson told Biotech Daily today that he was considering "multiple new directors" to fill the vacancies.

Asked why he wanted to remove the existing directors, Dr Jacobson said he wanted to "build the company up to pursue all of its opportunities, some of which are not being pursued".

"I believe the steps I've taken are the right thing to do. I believe I have a duty to shareholders," Dr Jacobson said.

"The current action is supported by more than 60 percent of shareholders," he said.

Dr Jacobson said the matters of concern were "very significant issues".

"I have legitimate genuine concerns as a director, in which they, as a majority [of the board] have not acted correctly," Dr Jacobson said.

Dr Jacobson said that his vision for Genetic Technologies after the meeting would see "a renewed effort in maximizing opportunities in generating revenue from our issued patents [which] recently have not been commercialized to their full potential."

"I'm talking about substantial revenues," Dr Jacobson said."

"CEOs are answerable to the board and the board is answerable to shareholders," Dr Jacobson said, questioning what was wrong with shareholders exerting their influence.

"The support is so broad that even if I didn't vote, I'd still win. They [my supporters] have the numbers to carry the day."

"Everyone who has raised this with me has urged me to stay on course."

Dr Jacobson acknowledged that his 40 percent shareholding was seen as an issue and said that despite his consent, nothing was done by the company to reduce it.

He said he supported a board discussion to sell down some of his holding.

"I supported that view. I said 'terrific, let's do it', but a year later nothing came of it," Dr Jacobson said.

He said he was committed to directors showing they supported their companies by buying shares, but if it would help Genetic Technologies, he was prepared to reduce his holding.

He said he was totally committed to the company.

The annual general meeting will be held on November 19.

Genetic Technologies fell 0.9 cents or 16.36 percent to 4.6 cents.

ANADIS

Anadis says a phase IV multi-site trial of its Biogard with Merck's anti-AIDS drug Isentress (raltegravir) has been approved.

Anadis said the study was designed to demonstrate that Biogard, supplementing Merck's raltegravir together and separately, can reduce gastro-intestinal immune activation and allow rebuilding of immune competence in those HIV patients with continuing HIV viral replication.

Anadis said raltegravir was the first of a new class of HIV drugs, integrase inhibitors, to receive US Food and Drug Administration approval.

Anadis chief executive officer Dr Zeil Rosenberg said the clinical study would "hopefully show that Biogard, the only approved oral, high affinity, [anti-lipo-polysaccharide] antibody formulation in the world today, can directly impact HIV disease progression by enhancing immune function and reducing local immune activation".

"Study data will hopefully show that BioGard is a safe and effective adjunctive treatment for all HIV/AIDS patients to enhance combination antiretroviral therapy," Dr Rosenberg said.

Anadis said the Institutional Review Board of Sydney's Australian National Center in HIV Epidemiology and Clinical Research and the University of New South Wales had approved the randomized double-blind placebo controlled study.

The company said the investigator-initiated study was sponsored by the Australian National Center in HIV Epidemiology and Clinical Research.

Anadis said Biogard was a novel oral therapy containing high affinity anti-lipo-polysaccharide antibodies and was recently approved for use by the Australian Therapeutic Goods Administration.

The company said HIV/AIDS was "one of the most devastating global diseases".

Anadis said 33 million people worldwide have HIV and 25 million have died of it since it was first recognized on December 1, 1981.

In the US, more than 1.1 million persons are living with HIV and there are 56,000 new cases annually.

Anadis said that during this past year, thanks in part to research sponsored by the US National Institutes of Health, there had been renewed recognition that the gastrointestinal system played a critical role in early infection and later development of HIV/AIDS.

In particular, the chronic immune activation in the gastrointestinal tract was a recognized cause of immune depletion, leading to treatment failure.

Anadis said it was in advanced discussion with leading researchers from the US National Institutes of Health and their collaborating clinical partners for additional, complementary studies of Biogard in patients with newly diagnosed disease.

Anadis's vice-president of business development Dr Oren Fuerst said Biogard "could potentially be used in both the developed and the developing world, and as an adjunct to all current antiretroviral treatments".

"While we could market Biogard on our own, we are in discussion with commercialization partners and we expect to announce such deals after we obtain the results of the … study, expected during calendar year 2009," Dr Fuerst said.

Anadis is focused on antigen-primed, dairy-derived health products.

Anadis said its antibody manufacturing technology enabled it to rapidly develop polyclonal antibody and other protein-based oral therapies to a range of important infectious and immune- mediated disease.

Anadis climbed one cent or 20 percent to six cents.

NOVOGEN

Novogen's 81 percent subsidiary Glycotex Inc has enrolled the first patient in a phase IIb study of GLYC-101.

Novogen said the trial of GLYC-101 for wound closure and cosmetic outcomes in cosmetic surgery patients undergoing carbon dioxide laser skin resurfacing on the lower eyelid area will enroll about 48 patients at one clinical trial site in Beverly Hills, California.

The company said a phase II pilot study investigating clinical outcomes and safety parameters of GLYC-101 at two doses compared to placebo was completed in April 2008.

In this new randomized, double-blind, placebo-controlled clinical study patients will be randomized to receive either GLYC-101 0.1% gel or GLYC-101 1.0% gel on one lower eyelid and placebo on the other lower eyelid applied topically to the laser-ablated area immediately following the procedure and for four consecutive days thereafter.

The primary efficacy endpoint of the study is time to wound healing and the secondary efficacy point is cosmetic outcomes, including scarring.

Novogen said the study would observe the effects of the topical agent over the course of one month following the initial treatment with the investigational compound and placebo.

Novogen fell three cents or three percent to 97 cents.

BENITEC

Benitec has raised $1.97 million through a placement of 43,793,232 shares and one for one free attaching options to Dr Christopher Bremner.

Dr Bremner is an existing shareholder who provided a $1 million loan to the company in 2006 when the share price was 2.6 cents (see Biotech Daily October 17, 2006).

Benitec chief executive officer Sue MacLeman said Dr Bremner had held onto the shares he acquired through that earlier investment.

Ms MacLeman said shareholder approval will be sought for the issue, other than an initial 9,022,222 shares and free attaching options to raise $406,000 which were able to be issued immediately without shareholder approval.

Ms MacLeman said the board expected "to reactivate the non-renounceable rights issue on completion of these negotiations".

The funds will be applied to general working capital including negotiations with Commonwealth Scientific and Industrial Research Organisation and intellectual property maintenance including activities associated with the US patent re-examination.

The shares will be issued at 4.5 cents and the attaching options will have an exercise price of 10 cents each with an expiry date of December 31, 2012.

Benitec fell 0.2 cents or 4.08 percent to 4.7 cents.

HEARTWARE

Heartware says stock holders overwhelmingly supported the relocation of the company to the US but more than 21 million proxy votes opposed the 2008 stock incentive plan.

Heartware said 126,680,956 proxy votes were cast in favor of the stock incentive plan resolution, with 21,415,954 proxy votes against.

The three court ordered meetings of shareholders, option holders and performance rights holders overwhelmingly supported the "redomiciliation" from Australia to the US.

Heartware said 159,153,370 shareholders votes and proxy votes (95.5%) supported the move with 82,929 shareholders votes and proxy votes (0.05%) against.

There was no opposition from option holders and performance rights holders.

Heartware was up five cents or 9.09 percent to 60 cents.

EVADO

Monash University's Centre of Cardiovascular Research and Education in Therapeutics has signed a contract to use Evado's web-based clinical trial software.

Evado said the Centre of Cardiovascular Research & Education in Therapeutics in Monash University's Department of Epidemiological Studies conducts academic and commercial animal and human clinical trials.

It also provides data management services for local and international research groups and works to improve clinical outcomes for Victorians through evidence based on clinical research.

The Centre's director Prof Henry Krum said Evado's software would provide "a very cost-effective mobile and web-based computing environment for collecting and managing all of our clinical trial data".

Evado said the Centre conducted trials for Bayer, Novartis, Merck & Co and other medical research institutions and would use Evado's system to collect and manage the data.

The company said the Centre of Cardiovascular Research and Education in Therapeutics had signed a reseller agreement for their commercial trials with the Evado software system.

Evado said its software "speeds up collection of data for clinical trials at 20 percent of the cost of other systems".

Evado is a private company.

ELLEX MEDICAL LASERS

Ellex has appointed Simon Luscombe as group chief executive officer, effective immediately, following the departure of Kevin McGuinness.

Ellex said Mr Luscombe was promoted from within the Ellex Group having served as the general manager of Ellex's Australian sales subsidiary, as well as vice-president of sales for Asia. He has been with Ellex since 2005.

Mr McGuinness joined Ellex in 2002 as chief financial officer and was appointed chief executive officer in June 2008.

Ellex said Mr Luscombe had "an outstanding track-record in sales and marketing within the ophthalmic industry".

The company said Mr Luscombe's sales career began in 1995 with Alcon Australia and in 2002 he was recruited by Advanced Medical Optics as national sales manager.

Ellex fell 2.5 cents or 11.11 percent to 20 cents.