Biotech Daily

Wednesday March 11, 2009

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PRANA UP 25%; LIVING CELL DOWN 22%**

*** FORTREND'S $12m PUTS PRIMA'S OVARIAN CANCER TRIAL ON TRACK**

*** BIOGUIDE BRIEF: IS THAT A FEINT WHIFF OF CASH IN THE AIR?**

*** PRANA'S PBT2 REPAIRS SYNAPSE DAMAGE IN MICE**

*** PHARMAXIS APPOINTS PRAXIS FRENCH DISTRIBUTOR**

*** ALCHEMIA REQUESTS IND APPLICATION TRADING HALT**

*** HITACHI TAKES JAPAN, KOREA OPTION ON FERMISCAN CANCER TEST**

*** EASTLAND TIGHTENS MANAGEMENT, LOSES TWO DIRECTORS**

*** INVESTORS BACK ADVANCED OCULAR'S IP SALE**

MARKET REPORT

The Australian stock market climbed 1.88 percent on Wednesday March 11, 2009 with the S&P ASX 200 up 59.9 points to 3,244.4 points. Eighteen of the Biotech Daily Top 40 stocks were up, nine fell, three traded unchanged and 10 were untraded.

Prana was best, up four cents or 25 percent to 20 cents with 87,500 shares traded, followed by Cytopia up 20.7 percent to seven cents, Novogen up 15.7 percent to 48 cents, Peplin up 14.3 percent to 56 cents and Bionomics up 10.5 percent to 21 cents.

Avexa, Benitec and Starpharma climbed more than nine percent; Genera was up 6.1 percent; Polartechnics rose 5.3 percent; Biota was up three percent; Chemgenex and Clinuvel rose more than two percent; with Acrux and Pharmaxis up more than one percent.

Living Cell led the falls, down 2.3 cents or 21.9 percent to 8.2 cents with 34,500 shares traded followed by Nanosonics and Psivida both down 10 percent to 27 cents and 90 cents respectively.

Labtech and Sunshine Heart both lost 8.33 percent; Viralytics fell 5.4 percent; Phosphagenics fell 4.6 percent; Cochlear was down 3.62 percent; with Cellestis and CSL down more than two percent; and Mesoblast and Resmed down less than one percent.

PRIMA BIOMED

The US-based Fortrend Securities will provide $12 million to Prima allowing the company to proceed to a pivotal phase IIb/III FDA-approved ovarian cancer trial for this year.

Prima executive director Martin Rogers told Biotech Daily that the US Food and Drug Administration had classified the CVac treatment as a "category III blood product" putting its pathway to registration between that of a new drug and a new device.

Mr Rogers said the trial would be in Australia, New Zealand and the US and much of the preliminary work had already been completed.

"We have to submit the paperwork and it will cost $US135,000 to put all the paperwork together for the FDA," Mr Rogers said.

"The trial could start possibly in the next three to six months," he said.

He said that should Prima be able to replicate the results from the 2006 phase IIa trial (BD: May 16, 2006; March 14, 2007) the Australian Therapeutic Goods Administration would allow the CVac to be prescribed to patients in Australia, "off-licence through the Australia New Zealand Gynaecological Oncology Group".

In May 2006 Prima said 21 percent or four of 21 patients responded to CVac treatment.

The principal investigator and director of cancer services at the Austin Hospital, Dr Paul Mitchell, said of the response rate: "To appreciate the significance of the results, it is important to realize that the population of patients enrolled in the trial of Cvac is made up of women with very advanced ovarian cancer. The standard therapy available to this patient population provides minimal benefit."

"Thus 15 percent of patients using a new treatment and achieving a clinical response or stabilization of disease is considered significant," Dr Mitchell said.

CVac is given after surgery and chemotherapy to delay relapse and control metastases.

The final results (BD: Mar 14, 2007) showed a major response with two women, a minor response in two women and a fifth patient responding but not to a defined statistical level.

The company proposed a multi-centre Australia and New Zealand pivotal trial to begin at the end of 2007, taking up to three years for final results.

The company could not raise the $10 million to fund that trial. Ata Gokyildirim was appointed non-executive chairman replacing chairman Eugene Kopp (BD: Dec 20, 2007) with Mr Rogers taking on the role of executive director.

Today, Mr Rogers said the $12 million funding would be provided by an equity draw-down facility, allowing Prima to place shares with Fortrend over the next three years.

Prima said the latest edition of the journal Nature America said CVac was one of the few selected cancer vaccines in late clinical trials and the only vaccine for ovarian cancer indication. Prima's scientific team is headed by Prof Ian Frazer.

Fortrend chief executive officer Joe Forster said his company was "very pleased to be able to help fund Prima and achieve its corporate objectives by supporting the commercialization of a much needed cancer vaccine for ovarian cancer sufferers".

Mr Rogers said the funding would allow the commercialization of CVac to proceed immediately and he was somewhat surprised that everything had fallen into place.

"I was aiming for this, but I wasn't sure we'd do it," Mr Rogers said.

"If we got another $10 million through the Commercial Ready Grants scheme it would make the world of difference," Mr Rogers said.

He said that last year the Federal Government's Department of Innovation had given an indication that Prima was likely to receive a grant for the CVac ovarian cancer treatment.

"We had submissions with Commercial Ready and it was a big shock when it was scrapped," he said.

Prima traded between 0.9 and 1.2 cents closing up 0.1 cents or 12.5 percent to 0.9 cents with 12,675,737 shares traded worth $129,994.

MARC SINATRA'S BIOGUIDE BRIEF: PRIMA BIOMED

Prima Biomed, a company I had written-off many moons ago, well and truly surprised me today by managing to secure $12 million via a funding facility with Fortrend Securities.

Now, before everybody gets excited, the provision of this facility does not mean that the current drought in biotech funding is over.

The standby subscription facility provided by Fortrend, whose clients include Rockeby Biomed and Acuvax is not the most sought after form of capital, but it isn't death-spiral financing in the form of resetting secured convertible notes, either.

On the other hand, when you have an unimpressive past, a phase II asset requiring significant amounts of money to develop and only $749,000 in the bank, you probably aren't going to attract ideal financing, anyway.

What I think this deal demonstrates is that there is a little bit of capital around for less-than-perfect or higher risk assets, whereas most of the capital raised in the last 12 months has gone to companies such as Heartware, Peplin and Chemgenex, who have late stage high quality assets.

Marc Sinatra

PRANA BIOTECHNOLOGY

Prana says mouse studies show that PBT2 for Alzheimer's disease, prevents the loss of synapses between neurons that underlies the process of neuro-degeneration.
Prana said transgenic Alzheimer's disease mice suffered a loss of synapses, which led to cognitive impairment because nerve cells could no longer communicate with each other.
The company said the new data showed that PBT2 could reverse the effect of amyloid beta protein toxicity on nerve cell synapse loss.
The director of the Mental Health Research Institute Prof Colin Masters said the study confirmed preclinical and clinical findings of PBT2 and the study "opened the pathway for PBT2 to prevent the damage caused by Abeta [amyloid beta] in the brain of a person with Alzheimer's disease and to improve cognitive function".
The effects of PBT2 in a phase II Alzheimer's disease trial were published in Lancet Neurology and presented at the 2008 International Conference on Alzheimer's disease.
Prana said at that time the 12-week phase IIa clinical trial of early stage Alzheimer's disease patients showed PBT2 to have statistically significant efficacy in some cognitive measures including "executive function" (BD: Jul 30, 2008).
The new data will be presented by Prof Masters at the 9th International Conference on Alzheimer's and Parkinson's disease in Prague on March 14, 2009.
In addition, the data will be presented by Dr Paul Adlard and Prof David Finklestein at the conference in a poster entitled "8-hydroxy quinoline effects on neuronal plasticity".
Prana chairman Geoffrey Kempler said the findings were "very exciting".
"We already knew that PBT2 could reduce the toxic effects of Abeta oligomer protein on Alzheimer disease patients, but this new data demonstrates that PBT2 can, in a mouse model, reverse the actual loss of nerve tissue that is believed to underlie Alzheimer's disease," Mr Kempler said.
"Given the lack of a disease-modifying drug available to patients, we are further encouraged by the enormous potential of PBT2," Mr Kempler said.
Prana climbed four cents or 25 percent to 20 cents.

PHARMAXIS

Pharmaxis has appointed Praxis Pharmaceutical France SARL as its French marketer and distributer for the asthma diagnostic tool, Aridol.

Pharmaxis said Praxis was "a recently established company created to introduce a portfolio of respiratory specialist products into the French pharmaceutical market".

Praxis will complete the reimbursement application for Aridol in France and thereafter market the product to hospital specialists.

Pharmaxis chief executive officer Dr Alan Robertson said the company was "looking forward to working with Praxis on developing the French market for Aridol".

"Aridol is a precisely engineered test that we believe will be an improvement on current practice," Dr Robertson said.

"Aridol improves the identification of bronchial hyper-responsiveness which is one of the hallmarks of asthma," he said.

About 3.1 million people in France are affected by asthma and the French bronchial challenge testing market was dominated by methacholine and more than 25,000 tests were conducted each year with little recent innovation in the field.

Pharmaxis said Aridol's ability to detect airway hyper-responsiveness in poorly controlled asthmatics provided information that was not previously available to physicians.

Aridol is approved for sale in Europe, Australia and Korea and is included in the Global Initiative for Asthma guidelines and the US Asthma Management Guidelines.

Pharmaxis was up two cents or 1.64 percent to $1.24.

ALCHEMIA

Alchemia has requested a trading halt pending an announcement on the filing of the its abbreviated new drug application with the US Food and Drug Administration.

Trading will resume on March 13, 2009 or on an earlier announcement.

Alchemia last traded at 17.5 cents.

FERMISCAN

Fermiscan says the Hitachi Chemical Company has an option to take up an exclusive licence to establish and operate the Fermiscan breast cancer test in Japan and Korea.

Fermiscan managing director David Young said he was "delighted to have the opportunity to work with a company of the calibre and experience of Hitachi Chemical".

"This is a major development for the Fermiscan breast cancer test," Mr Young said.

"Not only does Hitachi Chemical have the local market experience in Japan and Korea, it also has a rich talent pool of people and the technology and skills to assist Fermiscan with our commercial development in these two important countries," Mr Young said

The company said the option agreement required the completion of a feasibility study by Hitachi Chemical over the coming six months and subject to exercising the option Fermiscan and Hitachi Chemical would enter into negotiations for licensing the test in Japan and Korea.

Hitachi Chemical's head of new life science business development Hiroshi Ito said the number of breast cancer patients was "on a steep rise in Japan although the breast cancer screening rate grows slowly".

"Therefore, we hope the test can screen and identify more Japanese women with breast cancer at its early stages," Mr Ito said.

Fermiscan said the terms of the option and the licence agreements were confidential.

Fermiscan was unchanged at 18 cents.

EASTLAND MEDICAL

Eastland has appointed Michael Stewart to consult on planning the commercialization of the Artimist anti-malarial treatment and review the board and management.

Mr Stewart has a corporate and management background and has been involved in bilateral donor funded and World Bank co-financed aid projects.

Eastland said Mr Stewart has completed a review of the Company's activities including meetings in the UK and Germany with parties involved in its clinical trials, product manufacture and distribution.

Based on a recommendation to reduce its board, directors David Whitelaw and Peter Tiede have resigned. Mr Tiede continues as chief financial officer.

Eastland said it would restructure "around a four person board with a chief executive officer reporting to it.

The company said Douglas Sims, who "played a pivotal executive role in securing the rights to Artimist and Nicosorb", wanted a non-executive Board role at the successful conclusion of the clinical trials scheduled to commence "in the near term".

Eastland said it would in due course appoint an additional board member with the appropriate pharmaceutical industry experience.

Eastland was unchanged at 5.9 cents

ADVANCED OCULAR

Advanced Ocular shareholders overwhelmingly approved a resolution to sell the company's main assets triamcinolone acetonide to Alcon Research.

The triamcinolone acetonide intellectual property relates to the use of triamcinolone acetonide in various eye conditions.

Advanced Ocular said it would terminate its licence agreement with Alcon which has earned royalties from Alcon of approximately $161,000 between February 2008 and December 31, 2008.

In the notice for today's meeting Advanced Ocular said if approved it would be paid $US850,000 plus the royalties otherwise payable by Alcon for the quarter ending December 31, 2008, estimated at $US68,000.

More than 35.5 million proxy votes were in favor of the motion with 40,285 against and 22.4 million votes at the proxy's discretion.

Advanced Ocular is preparing a notice of meeting to approve a merger with International Formwork and Scaffolding expected in April with completion expected in May.

Advanced Ocular climbed 0.2 cents or 28.57 percent to 0.9 cents with 1.65 million shares traded.