Biotech Daily

Tuesday April 7, 2009

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP; CELLESTIS UP 14%, TISSUE DOWN 15%**

*** BIOGUIDE: PRANA AND THE DIFFERENCE A PBT2 DEAL WOULD MAKE**

*** STARPHARMA RAISES UP TO $4.6m FOR VIVAGEL, CONDOMS, RESEARCH**

*** ENTRUST BUYS DR TONY WARD'S 19.8% OF METABOLIC**

*** ANTEO REVIEW GENERATES FOREIGN PARTNER INTEREST**

*** CEPHALON INCREASES TO 26% OF ARANA**

*** VICTORIA AWARDS $1.2m TO 5 NEUROTRAUMA RESEARCHERS**

*** PHARMAXIS APPOINTS RICHARD VAN DEN BROEK DIRECTOR**

*** KARMELSONIX WINS EURO FROST & SULLIVAN GONG**

MARKET REPORT

The Australian stock market fell 1.34 percent on Tuesday April 7, 2009 with the S&P ASX 200 down 50.29 points to 3,706.3 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 11 fell, nine traded unchanged and seven were untraded.

Cellestis was best, up 32 cents or 14.22 percent to $2.57 with 58,873 shares traded followed by Genetic Technologies up 11.11 percent to five cents.

Clinuvel climbed 7.5 percent; Antisense was up 6.06 percent; Acrux and Progen were up five percent or more; Living Cell, Novogen, Optiscan and Polartechnics were up more than four percent; Mesoblast and Psivida climbed more than three percent; Circadian, CSL and Resmed were up more than one percent; with Cochlear up 0.1 percent.

Tissue Therapies led the falls, down three cents or 14.63 percent to 17.5 cents with 482,332 shares traded, followed by Bionomics down 10.9 percent to 20.5 cents.

Starpharma lost 10 percent; Cytopia and Nanosonics were down more than nine percent; Alchemia, Avexa and Prana fell five percent or more; Phosphagenics shed 2.94 percent; with Biota and Heartware down less than one percent.

MARC SINATRA'S BIOGUIDE: PRANA BIOTECHNOLOGY

Overview: Prana's trials and tribulations are aptly reflected in a graph of the company's share price since it was listed in mid-2000.

Hype regarding its potential Alzheimer's disease treatment, PBT1, drove the share price to more than $2.40 in late 2001. In 2005 Prana's share price was beaten down to 15 cents when it discontinued development of PBT1 a year after raising $US20 million for development of its successor, PBT2, from US institutions.

The development of PBT1's replacement, PBT2, its positive phase IIa trial results and the hope of a big pharmaceutical partner pushed the share price above 60 cents for the first time in four years. A year on, with little news, the share price is back in the doldrums and PBT2 is yet to be partnered.

Where are Prana and PBT2 headed?

Financials: Market cap: $42 million; cash: $7.9 million; last quarter cash burn: $1.8 million.

Directors: Executive chairman and chief executive officer: Geoffrey Kempler; non-executive directors: Dr George Mihaly, Brian Meltzer, Peter Marks.

The addition of a couple of new directors with strong drug development and partnering credentials would be desirable.

Products in Development:
1) PBT2: A metal protein attenuating compound (MPAC) that selectively binds metal ions. Amyloid-beta-peptide (Abeta) oligomers are generally thought to play a key role in Alzheimer's disease. Prana believes that through its metal ion binding ability, PBT2 prevents the formation and promotes the dissolution of amyloid-beta-peptide oligomers, particularly the key oligomer Abeta42. A phase IIa study of PBT2 in early Alzheimer's disease patients met its safety endpoint. It also showed significantly reduced cerebrospinal fluid concentrations of Abeta42 and positive changes in two of a battery of cognition tests. A Prana-commissioned independent report from US-based clinical researchers recently concluded that PBT2 was a suitable candidate for Huntington's disease clinical trials, in addition to Alzheimer's disease. Huntington's disease is another neurodegenerative disease associated with metals.

2) PBT427: Another MPAC in preclinical trials for Parkinson's disease. It has been shown in animal trials to protect the area of the brain affected in Parkinson's disease.

3) Other: Prana also has a further MPAC, an immunotherapy and a metallo-complexing agent, which inhibits the Abeta metal binding site, in late stage research for Alzheimer's disease. In addition, Prana is also developing Alzheimer's disease imaging compounds and possible treatments for cancer.

Development timelines were not available from the company.

Significant Product Markets: Twenty-six million people worldwide, as of 2006, and five million Americans, as of 2007, have Alzheimer's disease.

Decision Resources put 2007 sales of labeled Alzheimer's disease drugs at $US3 billion in the major markets, with forecast sales of $US9 billion in 2017. This fits well Datamonitor's forecast, which has sales at $US1.9 billion to $US12.7 billion for 2017.

Marketed Alzheimer's disease drugs only treat Alzheimer's disease symptoms. Numerous drugs aimed at various targets are in clinical trials that target the underlying cause of Alzheimer's disease. At least five of these drugs are in, or about to start, phase III trials.

Bapineuzumab (Elan & Wyeth) is an anti-Abeta antibody, while IgIV (Baxter) is composed of polyclonal antibodies. Results to date with Bapineuzumab have been disappointing. Semagacestat (Eli Lilly & Elan) is an inhibitor of beta-secretase which cleaves amyloid precursor protein into Abeta. Dimebon (Medivation) is thought to act as a mitochondrial stabilizer. It demonstrated significant improvements in all outcome measures in its initial pivotal trial and is currently undergoing a confirmatory phase III trial. Rember (Taurx), which inhibits tau protein aggregation and may also influence mitochondrial biochemical pathways, is expected to start phase III trials this year.

Opinion: Alzheimer's disease is a difficult indication to tackle. Although the aetiology of the disease is becoming better understood on a daily basis, significant knowledge gaps and alternate hypotheses abound. This is reflected in the large number of targets to which drugs are being developed and the failure of any company to date to develop one which has been approved for treating the underlying disease.

Most experts believe that no single drug will halt Alzheimer's disease and that a combination of drugs will prove the best approach. Although this may reduce the cash flows Prana could expect from PBT2, it also reduces risk.

The scientific rationale behind PBT2 is strong and well supported in the literature, despite the fact that another drug which targets Abeta, Tramiprosate, was discontinued after a phase III trial. Unlike PBT2, however, Tramiprosate did not demonstrate a significant effect on any aspect of cognition in its phase II trial.

Licencing deals often take six to 18 months to negotiate and it is now 12 months since PBT2's phase IIa results were released. If a deal is to be done, it should be done soon, otherwise the share price will continue to slide. Any deal would be important for a number of reasons, not the least of which is the positive signal it would provide regarding PBT2's future in such a difficult area.

A deal with PBT2 for Alzheimer's disease is also likely to increase interest in PBT2 for Huntington's disease and PBT427 for Parkinson's disease.

Based on a comparison to five similar companies with Alzheimer's disease therapeutic programs, I have calculated a value for Prana Biotechnology of 35 cents per share. A PBT2 licencing deal on reasonable terms would see the valuation rise considerably. Prana fell one cent or 5.26 percent to 18 cents.

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STARPHARMA

Starpharma has raised $4.3 million to $4.6 million through a private placement to existing and new institutional and sophisticated investors.

Starpharma said the placement had a first close of $3.1 million with the immediate issue of 11.8 million ordinary shares at 26 cents a share.

“To enable a major institutional participant to take up its maximum allocation, a second tranche of shares will be issued in May raising a further $1.2 million to $1.5 million,” Starpharma said.

The second tranche will be priced at the lesser of 26 cents a share and the volume weighted average price per share over the five trading days immediately prior to the settlement of the second tranche.

Starpharma said the two tranches of shares would be less than 15 percent of issued capital and shareholder approval was not required.

A share purchase plan will offer shares at 26 cents a share with a record date of today, April 7, 2009 providing Starpharma shareholders the opportunity to participate in the financing, without brokerage or transaction costs.

The company said the placement would boost the company’s cash reserves to more than $10 million and the additional funds would provide “sufficient operating capital for development activities to commercialize the Vivagel-coated condom with Starpharma’s partner SSL International Plc and to supplement grant funding to further advance the stand-alone Vivagel development program”.

Starpharma said the funds would also support further partnering and commercialization of its dendrimer applications and strengthen the company’s balance sheet by providing additional working capital.

The placement was led by Acorn Capital and an unnamed investment manager was among the new institutions to participate in the placement.

Starpharma chief executive officer Dr Jackie Fairley said the support from existing shareholders and new institutional shareholders reflected “a growing confidence in the commercial prospects for the Vivagel condom coating deal with SSL, the Vivagel stand-alone product and our broader product pipeline”.

Starpharma fell three cents or 10 percent to 27 cents.

METABOLIC, POLYNOVO

Entrust Funds Management has become a substantial shareholder in Metabolic, buying Dr Tony Moore’s 59,713,219 shares or 19.81 percent of the company.

Dr Moore told Biotech Daily that he wanted to see Metabolic’s 60 percent subsidiary company Polynovo “properly funded and the technology developed”.

He said he bought the shares on behalf of Entrust from former Metabolic director Franklyn Brazil at four cents a share and sold them at the same price to Entrust.

Mr Brazil was instrumental in preventing the December acquisition of Polynovo from Xceed Capital and Commonwealth Scientific and Industrial Research Organisation (BD: Nov 27, Dec 18, 2008). Polynovo chief executive officer Dr Ian Griffiths resigned unexpectedly in February (BD: Feb 6, 2009).

Dr Moore said that through Entrust he had found a way forward for Polynovo, with whom he has had a long-standing relationship.

The Perth-based Entrust is one of the three major shareholders in Progen and is believed to have voted against the Cytopia-led board spill (BD: Mar 27, 2009).

Metabolic fell 0.2 cents or 6.25 percent to three cents.

ANTEO DIAGNOSTICS

Anteo Diagnostics chief executive officer Dr Geoffrey Cumming has completed a review of the company establishing increased value potential in its existing programs.

Dr Cumming has been appointed a director of the company (formerly known as Biolayer) and told Biotech Daily the company had a “clear and immediate focus to extract value from what we have in-house”.

He said Anteo’s diagnostic technologies had “generated interest from potential commercial diagnostics partners” all of whom were off-shore.

In a media release to the ASX Anteo said Dr Cumming had assessed its assets and scientific platforms, strategy and underlying cost infrastructure.

Anteo said discussions had begun “with a number of potential commercial customers” who were assessing the Mix&Go technology for the improved immobilization of antibodies for use in pathology testing.

The company said it was pursuing arrangements with a number of third party commercial partners both locally and internationally to develop sensitive diagnostic assays.

Anteo said that the review process showed its underlying technology “contains far broader capability and commercial potential than just the immobilization of antibodies” and it would undertake further development work and strategies for the commercialization of these additional revenue streams.

Anteo said Mix&Go could be used to improve measured outcomes from a broad range of commercially available magnetic polystyrene beads for diagnostic testing including consistently lowering the level of antigen detection; binding antibodies to beads faster; improving the stability of antibodies bound to beads; and increasing the dynamic range of testing. These achievements were considered scientifically significant and aligned well with improvements sought by existing bead users.

The company said that the ovarian monitoring assay development activities with New Zealand Diagnostics subsidiary Manawatu Diagnostics were on track, with the next step to apply the assay to clinical samples provided by its joint venture partner to clinically validate the developed assay.

Anteo said its commercial agreement and collaboration with the Sydney-based Prince of Wales Medical Research Institute included an option to licence the Institute’s intellectual property.

The summary steps in producing a diagnostic test, were to isolate the proposed antigen (neuromelanin); produce antibodies to that antigen (anti-neuromelanin antibody); incorporate the antibody into a diagnostic test; and clinically validate the test.

The initial phase of the collaboration was for Anteo to reproduce the Prince of Wales Institute finding, that auto-antibodies to neuromelanin could be detected in patients with Parkinson’s disease, by use of its own proprietary technology.

The finding was not reproduced during the option period but Anteo and the Institute agreed to continue the collaboration to develop an assay and other diagnostic tools relating to the early detection of neurodegenerative diseases, including Parkinson’s disease.

Anteo climbed 0.1 cents or 16.67 percent to 0.7 cents with 1.5 million shares traded.

ARANA

Cephalon International Holdings increased its substantial shareholding in Arana from 56,535,626 shares (24.83%) to 58,996,994 shares (25.92) on April 3, 2009.

The change was through an increase in takeover acceptances (BD: Feb 27, Mar 2, 2009).

Arana was unchanged at $1.36.

VICTORIAN NEUROTRAUMA FELLOWSHIPS

Five Victorian researchers have been awarded Neurotrauma Initiative Fellowships.
Dr Nicole Bye, Dr Edwin Yan, Dr Cheryl Soo, have been awarded three-year, full-time fellowships worth $326,270 each; Dr Alistair Nichol was awarded a three-year part-time fellowship worth $163,135; and Kathleen Bakker won a two-year part-time fellowship worth $63,648 for their contributions to the field of neuroscience.
Victoria's Innovation Minister Gavin Jennings said the Victorian Government was "taking action to support medical research because of its important role in improving the health, prosperity and safety of all Victorians".
"These fellowships are designed to support researchers who show great potential in the early stages of their career," Mr Jennings said.
"The Neurotrauma Fellowships are part of a $63 million Brumby Government health research fund that supports Victorian scientists in their research into traumatic brain injury and spinal cord injury," Mr Jennings said.
"More than 700 Victorians suffer an acquired brain injury or spinal injury every year and this funding recognizes that it is a community problem that requires significant investment," he said.
The Victorian Government media release said Dr Nicole Bye was a post-doctoral research fellow at the Alfred Hospital's National Trauma Research Institute and would investigate how to promote the growth of new nerve cells after traumatic brain injury using a novel combination of proteins.
Also at the Alfred Hospital's National Trauma Research Institute Dr Edwin Yan will investigate biochemical brain responses following traumatic brain injury in order to develop better approaches to minimize further brain damage and neurological impairment.
Dr Cheryl Soo is a post-doctoral researcher at the Australian Centre for Child Neuropsychology Studies at the Murdoch Children's Research Institute at the Royal Children's Hospital and will adapt an established cognitive behavior therapy treatment, designed for young people with anxiety problems, to young people with a traumatic brain injury.
Senior lecturer in intensive care medicine at the Australian and New Zealand Intensive Care-Research Centre, Dr Alistair Nichol, conduct a clinical trial of early hypothermia, or lowered temperature, after traumatic brain injury to minimize further brain damage.
Senior clinical neuropsychologist at the Royal Children's Hospital Kathleen Bakker will investigate the impacts of smell impairments in children after traumatic brain injury and its role as a marker for damage to other key parts of the brain.

PHARMAXIS

Pharmaxis has appointed US life science investment manager Richard van den Broek as a director.
Pharmaxis said Mr van den Broek was the founder and managing partner of HSMR Advisors, a US-based fund manager with an investment emphasis on small and mid-cap biotechnology public companies.
HSMR Advisors has held a position on the Pharmaxis share register since 2005.
The company said Mr van den Broek worked on both the buy and sell side of the funds management industry holding senior positions at Cooper Hill Partners, Hambrecht & Quist, Merrill Lynch and Oppenheimer & Co.
Mr van den Broek is a chartered financial analyst and is a graduate of Harvard University.
Pharmaxis was unchanged at $1.91.

KARMELSONIX

Karmelsonix says it has won the 2009 European Frost & Sullivan product innovation of the year award for its Pulmotrack asthma monitor.

Karmelsonix said Pulmotrack was a noninvasive system that monitors wheezing and coughs continuously without requiring active patient cooperation.

The company said it was an alternative management tool for asthmatic patients who cannot perform spirometry.

Karmelsonix was up 0.1 cents or 5.26 percent to two cents with 1.2 million shares traded.