



Biotech Daily

Friday March 19, 2010

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: VIRALYTICS UP 14%; GENETIC TECHNO DOWN 10.5%**
- * **ALCHEMIA, EMISPHERE COLLABORATE ON ORAL FONDAPARINUX**
- * **NEUREN'S PERSEIS WINS \$194k GRANT FOR TREFOIL FACTORS**
- * **AVEXA REPAYS \$510k CSIRO HEP C LOAN**
- * **RESONANCE TEST FOR CARDIAC IRON LEVELS**
- * **BIOSIGNAL EGM BACKS MOVE TO MOVIES *WITH* ANTIMICROBIAL IP**
- * **PHARMAUST REQUESTS 'MATERIAL INVESTMENT' TRADING HALT**
- * **VIRALYTICS OUT OF THE GREY AND INTO THE PINK SHEETS**
- * **PLATYPUS TAKES 5% OF SIRTEX**
- * **GIACONDA SELLS MYOCONDA FOR \$928k**

MARKET REPORT

The Australian stock market climbed 0.19 percent on Friday March 19, 2010 with the S&P ASX 200 up 9.1 points to 4872.2 points. Seventeen of the Biotech Daily Top 40 stocks were up, seven fell, nine traded unchanged and seven were untraded.

Viralytics was best, up 0.8 cents or 13.8 percent to 6.6 cents with 7.4 million shares traded, followed by Sunshine Heart up 12.12 percent to 3.7 cents with 318,000 shares traded and Bone up 11.1 percent to 15 cents with 27,000 shares traded.

Phosphagenics climbed 8.2 percent; Prana was up 7.7 percent; Nanosonics was up 5.05 percent; with Bionomics, Chemgenex, Cochlear and Novogen up more than one percent. Nine companies climbed by less than one percent.

Genetic Technologies led the falls, down 0.4 cents or 10.5 percent to 3.4 cents with 270,000 shares traded, followed by Living Cell down 8.7 percent to 21 cents with 782,405 shares traded.

Phylogica lost five percent; Cathrx fell 4.35 percent; Impedimed shed 2.25 percent; with Pharmaxis, Resmed and Starpharma down by less than one percent.

ALCHEMIA

New Jersey's Emisphere Technologies and Alchemia will collaborate to develop an oral formulation of the anti-coagulant drug fondaparinux using Emisphere's Eligen technology. Alchemia chief executive officer Dr Pete Smith told Biotech Daily that the early development costs would be shared "fifty-fifty" then Alchemia would pay for an evaluation of the resulting formulation which was expected to be less than \$100,000.

Dr Smith said Alchemia would fund a phase I pharmacokinetic study if the evaluation was successful.

He said if all went well the next step would be a 505B2 application to the US Food and Drug Administration, effectively seeking approval for a known drug administered by a different route.

Dr Smith said fondaparinux had a 100 percent bioavailability when administered subcutaneously, but a negligible oral bioavailability of less than one percent.

In a media release Alchemia said Emisphere had a broad-based drug delivery platform, known as the Eligen, using proprietary, synthetic carriers to enhance the oral bioavailability of a drug without altering its chemical form or biological activity.

Alchemia said fondaparinux was an anti-coagulant used for the prevention of deep vein thrombosis and was marketed in injectable form as Arixtra by Glaxosmithkline.

The company said Arixtra had been off patent since 2002 but, due to the complexity of its synthesis, there was no approved generic or alternative source of commercial scale active pharmaceutical ingredient.

Alchemia said it had developed a novel, patent-protected, synthesis for the manufacture of fondaparinux at commercial scale.

In March 2009, Alchemia's manufacturing and U.S. marketing partner, Dr Reddy's Laboratories submitted an abbreviated new drug application to the FDA for a generic version of the injectable form of fondaparinux (BD: Mar 13, 2009).

The application was accepted in May 2009 and Dr Smith said approval was expected at any time (BD: May 11, 2009).

Emisphere chief executive officer Michael Novinski said an oral formulation of fondaparinux "could dramatically increase the market potential for fondaparinux".

"Based on what we know from our experience with other chemically-related anti-coagulants, the profile of fondaparinux should fit very well with the Eligen technology given its half-life and safety profile," Mr Novinski said.

"Although developing an oral formulation of an injectable compound is always challenging, this project could produce substantial benefits for the medical community," Mr Novinski said.

"The combination of Emisphere's delivery technology and Alchemia's fondaparinux may ultimately allow us to bring an oral anti-coagulant to market in an accelerated fashion," Mr Novinski said.

Alchemia's Dr Smith said preclinical data suggested that enhanced levels of oral absorption couldn't be achieved for fondaparinux.

"If we can successfully optimize the dose formulated with the Eligen technology from Emisphere it would open up a host of medically and commercially compelling opportunities for fondaparinux," Dr Smith said.

"We will initially evaluate a number of different formulations in order to optimize oral bioavailability and pharmacokinetics, with the aim of then rapidly moving into human clinical studies."

Alchemia was unchanged at 67 cents.

NEUREN PHARMACEUTICALS

Neuren says subsidiary company Perseis Therapeutics has been awarded \$NZ250,000 (\$A194,000) for its trefoil factor (TFF) inhibition program.

The grant was awarded by the New Zealand Government's Foundation for Research, Science and Technology

Perseis was founded in 2009 by Neuren Pharmaceuticals and the New Zealand Breast Cancer Research Trust to develop antibody therapeutics to trefoil factors 1 and 3 and growth hormone for the treatment of breast and other cancers.

Neuren said trefoil factors were estrogen-regulated proteins which acted as growth factors, promoting cell survival and migration.

The company said trefoil factors have been linked to a number of cancers and found to play an important role in the growth and metastasis of solid tumors.

Neuren said TFF-1 was expressed in up to 68 percent of breast cancers and had been detected in the blood of patients who had residual disease after treatment and reportedly predicted survival in breast cancer patients with metastatic disease.

An article entitled 'Trefoil factor-1 enhances oncogenicity of mammary carcinoma cells' by Amriy N was published in the journal Endocrinology in 2009.

An abstract is at <http://endo.endojournals.org/cgi/content/abstract/en.2009-0066v1>.

Neuren said the inhibition of trefoil factor 3 has been shown to be effective in the treatment of tamoxifen-resistant breast cancer cells.

The company says tamoxifen resistance was "a major problem in breast cancer therapy and responsible for a large proportion of treatment failures".

Neuren said Perseis' chief scientific officer Prof Peter Lobie was one of the first in the field to identify this association and Perseis had rights to a number of patents for the treatment of cancers based on the work of Prof Lobie and his colleagues.

Perseis chief executive officer Dr Parmjot Bains said the support from the Foundation for Research, Science and Technology would enable her company "to continue to progress this very exciting and unique [intellectual property] in the oncology field".

Breast Cancer Research Trust chief executive officer Tony Moffat said his organization's goal was "to find a cure for breast cancer within 10 years".

Neuren was unchanged at 3.3 cents.

AVEXA

Avexa says it has repaid a convertible loan from the Commonwealth Scientific and Industrial Research Organisation for its hepatitis C Virus program.

Avexa said it elected to exit the CSIRO Australian Growth Partnership Program and independently fund any ongoing research with the Organisation.

Avexa chief executive officer Dr Julian Chick told Biotech Daily that the program offered up to \$2 million but the company had only used part of the facility and would repay the balance of \$510,000.

Dr Chick said the early in-vitro pre-clinical development work was positive and on-going.

In a media release to the ASX Avexa said it would retain all rights to the hepatitis C program and the intellectual property generated from the program.

The company said that during the past years the two organizations collaborated in the area of hepatitis C.

Avexa said the loan facility provided "important funding certainty" for the program in 2009.

Avexa said it would continue its collaborative research with CSIRO in the area of infectious diseases, such as hepatitis C and HIV.

Avexa was unchanged at 13.5 cents with 1.6 million shares traded.

RESONANCE HEALTH

Resonance says it has launched a new service to assess the risk of cardiac iron loading for patients with iron overload disorders.

The company said the test would be delivered through the Resonance Health image analysis service centre in Perth.

Resonance said the test expanded its quantitative radiological image analysis services.

The company said that while the liver was the primary site of iron storage, "once a certain threshold of liver iron is exceeded iron can begin to accumulate in the heart and other organs".

Resonance said the assessment of an imaging parameter known as T2-Star (T2*) was widely used to provide an indirect measure of cardiac iron.

The company said the cardiac T2-Star test complemented the existing Ferriscan liver iron test providing clinicians with a more comprehensive picture of the iron overload status of the patient.

Resonance said the Ferriscan liver iron test was launched in 2005 and was its core product available in more than 20 countries.

The company said the Cardiac T2-Star analysis service was being offered with a Ferriscan liver iron test to customers in Australia, NZ and countries covered by the Conformité Européenne (CE) mark.

Resonance was untraded at 2.7 cents.

BIOSIGNAL

Biosignal shareholders have voted in favor of all resolutions to become RGM entertainment group, except for the assignment of the core intellectual property.

Last year Empire Investments a company associated with Dr Paul D'Silva took control of Biosignal's board (BD: Apr 28; May 6, 7; Dec 17, 2009).

Dr D'Silva was Pharmaust's managing director until he resigned on August 3, 2007 and has had a long standing relationship with Commonwealth Biotechnology and is currently a director of that company.

Biosignal shareholders were asked to approve a series of resolutions turning the company from one developing the eastern Australian seaweed *Delisea pulchra* which produces natural furanones that disable bacterial ability to colonize through interrupting microbial signaling into the talent management and executive production company RGM Entertainment (BD: Jul 31, 2009).

All resolutions on the change of name, consolidation of share capital election of RGM representatives to the board, share issues and capital raisings were passed.

The only resolution to fail was on assigning the Biosignal intellectual property to Dr D'Silva's Commonwealth Biotechnology, which was lost with 18,868,707 proxy votes in favor and 37,366,256 proxy votes opposed.

Biosignal was placed in a voluntary suspension in order to comply with ASX Listing Rules following the change of business direction.

Biosignal last traded at 1.5 cents.

PHARMAUST

Pharmaust has requested a trading halt pending an announcement on "a material investment".

Trading will resume on March 23, 2010 or on an earlier announcement.

Pharmaust last traded at five cents.

VIRALYTICS

The US Financial Industry and Regulatory Authority has approved an upgrade of Viralytics American depository receipts from the Grey market to the Pink Sheets market.

Viralytics' managing director Bryan Dulhunty said the move "simplifies the process for American investors to buy shares in the company".

Mr Dulhunty said the US was the biggest biotechnology and pharmaceutical market in the world "and we continue to build both our clinical development and investor presence in this market".

He said the company had two US-based directors, its lead product Cavatak was produced in the US and a US Food and Drug Administration investigational new drug application program was underway.

"The market tier upgrade and continuous two-way quote by a [Financial Industry and Regulatory Authority]-registered market maker provides for increased transparency and understanding for our shareholders and supporters in the US," Mr Dulhunty said.

Viralytics said Viriathus Capital was its advisor through the process and would continue to provide strategic advice regarding US capital markets.

Viralytics was up 0.8 cents or 13.8 percent to 6.6 cents with 7.4 million shares traded.

SIRTEX

Platypus Asset Management has become a substantial shareholder in Sirtex with a holding of 2,801,137 shares or 5.02 percent.

Platypus bought the shares between October 17, 2009 and March 17, 2010 at an average price of \$5.18.

Platypus chief operating officer Gary Adamson issued the initial substantial shareholder notice for the company based at Suite 1602, 1 Alfred Street, Sydney.

Sirtex was up six cents or 0.98 percent to \$6.20.

GIACONDA

Giaconda has agreed sell its Myoconda intellectual property to Australian Medical Therapy Investments for \$928,000 (excluding GST) plus five percent of net sales (BD: Mar 9, 2010).

Giaconda was untraded at 4.2 cents.