Biotech Daily

Tuesday June 17, 2008

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECHS DOWN: OPTISCAN UP 19.5%, TISSUE THERAPIES DOWN 20%**

*** CHEMGENEX DRUG EFFICACY IN 2nd LEUKEMIA INDICATION; IP EGM**

*** VICTORIA, NEW ZEALAND CREATE $30m COMMERCIALIZATION FUND**

*** PHARMAXIS BRONCHITOL AVAILABLE VIA COMPASSION PROGRAM**

*** PROTEOME HITS BECTON DICKINSON MILESTONE**

*** OPTISCAN WINS MINISTER CARR'S SUPPORT, RAISES $3m**

*** FDA ALLOWS HALCYGEN'S IND APPLICATION**

*** WHO RENAMES CLINUVEL'S CUV1647 'AFAMELANOTIDE'**

*** FMR, FIDELITY DROPS 1% MORE OF COCHLEAR**

*** KARMELSONIX SAYS SOUND DETECTS BROCHO-DILATION**

*** CATHRX APPOINTS BOSTON SCIENTIFIC'S GED WALLACE PRESIDENT**

*** ASIC APPROVES CLINICAL CELL NAME CHANGE TO AVITA**

*** SUSPENDED PSIVIDA TO BE REPLACED BY PSIVIDA CORP**

*** AUSBIOTECH INAUGURATES BIO-BEERS**

MARKET REPORT

The Australian stock market climbed 0.9 percent on Tuesday June 17, 2008 with the All Ordinaries up 49.6 points to 5,525.9 points. Thirteen of the Biotech Daily Top 40 stocks were up, 17 fell, six were unchanged and four were untraded.

Optiscan was best, up four cents or 19.51 percent to 24.5 cents on modest volumes, followed by Polartechnics up 18.18 percent to 13 cents and Portland up 12.9 percent to 3.5 cents. Cellestis climbed 9.23 percent; Starpharma was up 6.9 percent; Bionomics and Pharmaxis were up more than five percent; Arana, Chemgenex, Phylogica and Ventracor climbed more than three percent; Cochlear and Cytopia rose more than two percent; with Acrux up 1.08 percent.

Tissue Therapies led the falls, down 2.5 cents or 20.0 percent to 10 cents, followed by Sunshine Heart down 9.09 percent to five cents. Peplin lost 7.5 percent; Alchemia fell five percent; Circadian, Genetic Technologies and Sirtex fell more than four percent; Universal Biosensors was down 3.41 percent; Benitec, Neuren, Prana and Resmed shed more than two percent; with Antisense, Avexa, Biota, CSL, Living Cell and Progen down more than one percent.

CHEMGENEX

Chemgenex says its lead drug has shown efficacy in chronic myeloid leukemia patients who have failed therapy with two or more tyrosine kinase inhibitors.

Chemgenex said it was the first data on omacetaxine mepesuccinate (formerly known as Ceflatonin) in a phase II trial of patients with or without Bcr-Abl mutations.

Chemgenex said the data, presented at the European Haematology Association congress in Copenhagen, was separate from and complemented the findings from the phase II/III trial of omacetaxine mepesuccinate in chronic myeloid leukemia patients with the T315I mutation.

The announcement was made to the ASX yesterday (June 16) but Biotech Daily was unable to contact Chemgenex for clarification of the data prior to publication.

Of the 28 patients enrolled in the trial, the poster session data related to 12 evaluable patients: four in chronic phase, two in accelerated phase and six in blast phase.

Chemgenex said there were haematologic responses in all chronic and accelerated phase patients, with complete haematologic responses in three out of four chronic phase patients and both accelerated phase patients.

The company said the study showed cytogenetic responses in one of four chronic phase patients and one of two accelerated phase patients and two of six blast phase patients had haematological responses.

Chemgenex said omacetaxine therapy was associated with myelosuppression which was manageable and reversible.

Chemgenex chief executive officer Dr Greg Collier said the company was “delighted with this very positive early data from the multiple [tyrosine kinase inhibitors] resistance trial”.

Dr Collier said the poster at the American Society of Clinical Oncology conference in Chicago [see Biotech Daily; June 3, 2008] reported durable clinical responses in chronic myeloid leukemia patients with the T315I mutation.

He said the new data supported the belief that omacetaxine, acting through an independent mechanism of action, offered a new therapeutic alternative to the growing number of chronic myeloid leukemia patients who became resistant to tyrosine kinase inhibitor therapy.

Chemgenex said tyrosine kinase inhibitors such as imatinib, dasatinib and nilotinib target the Bcr-Abl protein and are the current approved therapies for chronic myeloid leukemia, but an increasing number of patients are developing resistance to these agents.

“The knowledge we are gaining from our two major clinical trials gives us confidence in the potential of omacetaxine to treat CML patients for whom there are few treatment options due to the limitations of tyrosine kinase inhibitor treatments,” said Dr. Collier.

He said the company was “on course” to begin filing a rolling new drug application to the US Food and Drug Administration in mid 2008, starting with the non-clinical section.

He said Chemgenex was on track to achieve its enrolment targets within the year and to complete the rolling new drug submission in mid 2009.

Separately, Chemgenex said that an extraordinary general meeting would be held to vote on the issue of 37,235,343 ordinary shares to Stragen International NV to acquire full control of the global intellectual property and commercialization rights of omacetaxine mepesuccinate (see Biotech Daily; June 10, 2008).

The meeting will be held at the offices of GBS Venture Partners at Level 5, 71 Collins Street, Melbourne on July 22, 2008 at 11am.

Chemgenex was up three cents or three percent to $1.03.

VICTORIA, NEW ZEALAND

Victoria and New Zealand have created a $30 million trans-Tasman research commercialization fund for universities.

Victoria's Premier John Brumby and New Zealand's Minister for Economic Development Pete Hodgson said the fund would "drive cross-disciplinary research into developing life-saving medical technology".

In San Diego for BIO-2008, Mr Brumby said the fund would be based in Melbourne with the Governments of New Zealand and South Australia also contributing.

"Research is expected to include antibodies for treatment of cancer and other serious diseases and regenerative medical treatments for conditions such as neurodegenerative disorders, diabetes, arthritis, musculo-skeletal and cardiovascular diseases," Mr Brumby said.

Innovation Minister Gavin Jennings said the venture involved Monash University, the University of Auckland and the University of Adelaide, Flinders University and University of South Australia.

West Australian-based superannuation fund Westscheme is committing $30 million to help fund early stage development of start-up companies that will commercialize the research.

Monash University Vice-Chancellor Prof Richard Larkins said the fund would provide capital to support the initial development of new technologies and business opportunities.

"Having access to true early-stage capital will definitely assist Monash to continue its strong history of developing spinout companies such as Monash IVF Australia and Acrux Limited," Prof Larkins said.

PHARMAXIS

Pharmaxis has appointed the UK-based Idis to manage and provide eligible patients access to Bronchitol through a named patient program.

Pharmaxis said the compassionate use program would allow patients who are unable to participate in Pharmaxis clinical trials but are considered by their physician to be suffering from a clinical condition for which no satisfactory authorized alternative exists, to receive access to Bronchitol on a named patient basis.

The program will establish a common approach to the use and distribution of Bronchitol and the eligibility of patients.

Pharmaxis chief executive officer Dr Alan Robertson told Biotech Daily that any patient suffering from a mucous condition including emphysema, bronchitis or cystic fibrosis could apply for the program.

"Idis is a partner of choice for major global pharmaceutical companies in providing ethical named patient access to medicines in countries where the product is yet to be authorized," Dr Robertson said in a release to the ASX.

"Bronchitol will be made available to people with a chronically or seriously debilitating, or life threatening condition who cannot be treated satisfactorily by an authorized medicine," Dr Robertson said.

He said Idis managed named-patient programs in more than 100 countries and was recognized for its rigorous capture of pharmaco-vigilance information and quality doctor education programs.

"We are pleased to be able to offer the option of Bronchitol to physicians with patients in urgent need," said Dr Robertson.

Pharmaxis said Bronchitol was in the final clinical trials for the treatment of the chronic lung conditions cystic fibrosis and bronchiectasis.

Pharmaxis was up 8.5 cents or 5.63 percent to $1.595.

PROTEOME

Proteome has completed the next milestone for the feasibility stage of its tuberculosis collaboration with Becton Dickinson.

In completing this milestone, Proteome has defined a sample-processing strategy for application to an in-field diagnostic test of sputum and/or blood.

The milestone relates to treating the sample to make it compatible in the point-of-care test.

Proteome chief executive officer Dr Jenny Harry said the company's tuberculosis team had made continual advances on the program.

The milestone triggers a further payment to Proteome towards completion of the feasibility stage of test development.

Proteome and Becton Dickinson began a collaboration and licencing deal for the development and commercialization of tuberculosis diagnostic tests in July 2007.

Proteome said rapid and accurate diagnosis was "critical to treat TB patients effectively and to arrest disease transmission".

The primary need is for simple confirmatory and screening tests to distinguish active TB from other conditions with similar symptoms.

Proteome and Becton Dickinson aim to develop Proteome's technology to allow direct detection of active tuberculosis in sputum and/or blood in a cost-effective point-of-care test for rapid diagnosis.

Proteome was unchanged at 13 cents.

OPTISCAN

The Federal Minister for Innovation, Industry, Science and Research Senator Kim Carr has backed Optiscan's confocal microscope as the company raises $3 million.

Senator Carr said in San Diego that the Optiscan microscopes would be installed in three Victorian hospitals.

"This is innovation at its best and I am proud to be announcing such an Australian success story while I'm here in San Diego with this strong Australian delegation at BIO 2008," Senator Carr said.

"This new Optiscan microscope can be used to detect cancers and gastrointestinal disease at a very early stage. Three Melbourne hospitals, the Western and Box Hill Hospitals and the Monash Medical Centre will be added to the 30 hospital rollout worldwide," Senator Carr said.

The Optiscan microscope offers doctors magnifications of 1000 times compared to 30-40 times in traditional endoscopy allowing clinicians to detect gastrointestinal tract cancers and diseases without the need for potentially error-prone and invasive biopsies.

"This is also a breakthrough in the diagnosis of gastrointestinal disease in children, because it can provide diagnosis and treatment in the one visit … rather than the child having to endure separate surgical procedures for a biopsy and treatment," he said.

Separately Optiscan said it had placed 13.04 million shares, raising $3.0 million at 23 cents a share.

Optiscan chief financial officer Bruce Andrew told Biotech Daily that directors Grant Latta, Tony Rogers and Vicki Tutungi participated in the placement, collectively buying about $500,000 of shares, subject to shareholder approval.

Optiscan said the funds would enhance its cash position and the development of plans to introduce two new medical products into the market in its own name.

Optiscan climbed four cents or 19.51 percent to 24.5 cents.

HALCYGEN

The US Food and Drug Administration has approved Halcygen's pivotal pharmacokinetic studies of Suba-itraconazole.

Halcygen said the FDA allowance to proceed came 30 days after the company submitted its investigational new drug application and the approval was "a major milestone in the registration strategy".

The company said the study would examine the bioequivalence of Halcygen's Suba-itraconazole and the market-leading product Sporanox (itraconazole).

Halcygen chief executive officer Dr Roger Aston said that initiation of pivotal studies in the US was "one of Halcygen's biggest milestones".

"Registration of our product in the US after the pivotal studies will enable product sales in the US and in many other countries without further clinical trials," Dr Aston said.

"Recruitment for the first [pharmacokinetic] study is underway," he said.

Halcygen said it had clinically evaluated Suba-itraconazole in five successful pharmacokinetic studies in Australia.

The company said the studies demonstrated that Halcygen's formulation has significantly improved bioavailability or absorption by the gastrointestinal track compared with the market leader, enabling the use of a lower dose of the drug.

Halcygen's formulation also provides for more stable blood levels compared to Sporanox.

The current global market for itraconazole is more than $US600 million a year.

Halcygen climbed 10 cents or 33.33 percent to 40 cents.

CLINUVEL

The World Health Organisation has designated the name "afamelanotide" for Clinuvel's photo-protective drug CUV1647.

Clinuvel said generic names issued by the World Health Organisation (WHO) were international and non-proprietary in nature.

Afamelanotide will be universally used to describe the active pharmaceutical substance Nle4-D-Phe7 alpha-melanocyte stimulating hormone developed by Clinuvel.

Clinuvel said that with the designation, afamelanotide becomes the universally applicable generic name for Nle4-D-Phe7 alpha-melanocyte stimulating hormone, the molecular name used so far for the drug.

Afamelanotide will be included in the international list of acknowledged pharmaceuticals, medicinal label and product information.

Clinuvel chief executive officer Dr Philippe Wolgen said the next step was to arrive at a brand name which will fully cover the properties and medical benefits of afamelanotide.

Clinuvel was unchanged at 36 cents.

COCHLEAR

The US based FMR Corp and Fidelity Investments have again reduced their substantial shareholder in Cochlear from 5,553,327 shares (9.98%) to 4,931,724 shares (8.87%) on June 13, 2008.

FMR Corp and Fidelity reduced its holding in Cochlear by one percent on June 4, 2008.

FMR and Fidelity had been increasing its holding in both Cochlear and CSL.

This is the second reduction in Cochlear since Biotech Daily begun monitoring the holdings.

FMR and Fidelity have not changed their CSL holdings.

Cochlear climbed $1.25 or 2.61 percent to $49.06.

KARMELSONIX

Karmelsonix says a study at Melbourne's Alfred Hospital confirmed that sound transmission can predictably detect dilatation of the bronchial airways.

The study applied the company's acoustic transmission technology to seven asthma patients before and after administration of a broncho-dilating aerosolized drug and was compared against the standard spirometric measurement of the forced expiratory volume (FEV1.0) which requires substantial patient cooperation.

Karmelsonix said the study "confirmed that sound transmission in a certain frequency band can positively and predictably detect dilatation of the bronchial airways".

The company said the acoustic technology complemented the quantitative wheeze detection technology implemented in the US Food and Drug Administration-approved Pulmotrack monitor.

Karmelsonix' chief medical officer Prof Noam Gavriely said the study showed that active acoustic technology, which requires no patient cooperation, can be used to monitor the status of the airways of asthmatics.

He said the next components of the study of assessing sound transmission during bronchial provocation tests and assessing sound transmission in moderate and severe asthma patients presenting to the hospital's emergency department were underway.

The study is a milestone in the development program of the Acoustic Severe Asthma Monitor funded in part by the Victoria-Israel Technology Fund.

Karmelsonix fell half a cent or five percent to 9.5 cents.

CATHRX

Cathrx has appointed Gerard (Ged) Wallace as president to lead its marketing initiatives and business development activities.

Cathrx said Mr Wallace would initially be based in Europe and has had a successful career with Fortune 500 companies.

The company said Mr Wallace had experience in building and managing large global teams and driving global sales.

He was most recently president of Boston Scientific Corporation, Europe, Middle East and Africa responsible for their total business and significant employee base.

Prior to Boston Scientific Mr Wallace worked for Baxter International for 27 years and was president of Baxter Healthcare Asia.

Cathrx chief executive officer Neil Anderson said it was fortunate that Mr Wallace had been appointed as the company shows its Conformitée Européenne (CE) marked products for the first time at the Cardiostim World Congress in Cardiac Electrophysiology and Cardiac Techniques June 18 to 21, 2008 in Nice on the French Riviera.

Cathrx was unchanged at 90 cents.

CLINICAL CELL, AVITA

The Australian Securities and Investments Commission has approved Clinical Cell Culture's change of company name to Avita Medical.

Following shareholder approval of a 10-for-one share consolidation, trading in the reorganized capital commenced on June 10, 2008 under the code CCEDA on a deferred settlement basis.

The name change to Avita Medical will take effect on the ASX on June 26, 2008 and the company will trade under the code AVH.

Clinical Cell fell two cents or 17.39 percent to 9.5 cents.

PSIVIDA

Psivida was suspended from trade on June 11, 2008 and will be removed from the official list of the ASX on June 20.
Psivida said the successor entity Psivida Corp will trade under the code PVA.
Psivida last traded at 9.3 cents.

AUSBIOTECH

Ausbiotech has initiated an informal “Bio-Beers” after work drink at the appropriately selected Croft Institute.
Ausbiotech says industry personnel are invited to join management, staff and industry colleagues for a social drink in a relaxed atmosphere, with no formal presentations.
The inaugural Bio-Beers will be held on Thursday June 19, 2008 at the Croft Institute,21 Croft Alley in Melbourne from 6pm.
Croft Alley is off Payne’s Lane which is off Little Bourke Street between Exhibition and Russell Streets.
Registration is not required