Biotech Daily

Monday December 17, 2012

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: LIVING CELL UP 8%, ALLIED HEALTH DOWN 12.5%**

*** LIVING CELL DEAL WITH OTSUKA FOR NTCELL FOR NEUROLOGY**

*** ALLIED PLACEMENT RAISES $1.7m; SHARE PLAN**

*** INVION MEETS FDA FOR INV103 FOR LUPUS**

*** IMMURON MOUSE STUDIES BACK IMM-529 FOR CLOSTRIDIUM DIFFICILE**

*** EUROPEAN COMMITTEE REBUFFS ANTISENSE PARTNER ISIS, GENZYME**

*** UNIVERSAL BIOSENSORS PLAN RAISES $1.2m, TOTAL RAISED $13.2m**

*** CONSEGNA PLACEMENT RAISES $500k, SHARE PLAN FOR $250k MORE**

*** FORTREND TAKES 9% OF AGENIX**

*** CHAIRMAN ANDREW KROGER TAKES 23% OF CRYOSITE**

*** ALCHEMIA TAKES NASDAQ LISTING, IPO TO SUSPENSION**

*** STARPHARMA APPOINTS EVE WILLIAMSON V-P BUSINESS DEVELOPMENT**

*** WEHI'S PROF PETER COLMAN WINS INAUGURAL BRAGG MEDAL**

MARKET REPORT

The Australian stock market fell 0.21 percent on Monday December 17, 2012 with the S&P ASX 200 down 9.7 points to 4,573.4 points. Eight of the Biotech Daily Top 40 stocks were up, 15 fell, nine traded unchanged and eight were untraded.

Living Cell was the best, up 0.4 cents or 8.2 percent to 5.3 cents with one million shares traded. Psivida rose two percent; Anteo; Heartware, Resmed, Universal Biosensors and Viralytics were up more than one percent; with Clinuvel, Cochlear and Sirtex up by less than one percent.

Allied Health led the falls, down 0.3 cents or 12.5 percent to 2.1 cents with 5.7 million shares traded. Antisense lost 7.7 percent; Benitec and Cellmid were both down 6.7 percent; Prima fell 4.35 percent; Impedimed was down 3.2 percent; Mesoblast, Prana and Sunshine Heart shed more than two percent; Acrux, CSL and Nanosonics were down more than one percent; with Pharmaxis, QRX, Reva and Starpharma down by less than one percent.

LIVING CELL TECHNOLOGIES

Living Cell says that Japan's Otsuka Pharmaceutical Factory will co-develop NTCell for the treatment of Parkinson's disease and other neurological disorders.

Living Cell said it would receive an upfront payment of $3 million within 30 days of signing and Otsuka would fund all development costs, estimated at $2 million, to complete the previously announced phase I trial of NTCell in Parkinson's disease.

Living Cell said it would receive a further milestone payment of $2 million when the first patient in the phase I Parkinson's trial had been safely implanted with NTCell, expected by July 2013.

The company said that in return it had granted Otsuka an exclusive option to jointly develop and commercialize NTCell in Parkinson's and other neurological diseases, including hearing loss, through Diatranz Otsuka, the 50-50 joint venture formed between Living Cell and Otsuka.

Living Cell said that if Otsuka exercized this option it would subscribe for $20 million of additional equity into Diatranz Otsuka to fund the ongoing development of NTCell in Parkinson's disease through to market approval and to further develop NTCell in other neurological diseases.

The company said that at the same time, it would transfer the intellectual property for therapeutic use of NTCell in neurological disease and hearing loss into Diatranz Otsuka, creating a new $40 million asset in the Diatranz Otsuka joint venture, with Otsuka and Living Cell remaining equal shareholders.

Living Cell said it would retain the exclusive, perpetual licence to develop NTCell for the treatment of all other, non-neurological diseases.

The deal is similar to one struck with Otsuka for Diabecell last year (BD: Oct 19, 2011).

The company said that the agreement ensured that, if the phase I clinical trials were successful, the development of NTCell as a treatment for Parkinson's disease would be fully funded through to market approval.

Living Cell managing director Dr Andrea Grant said the company would be able to bring NTCell to patients and the market without further recourse to shareholders' funds, while retaining 50 percent of the commercial return.

Otsuka executive senior managing director Hiromi Yoshikawa said the partnership with Living Cell in Diabecell "delivered on all fronts in the last year".

"NTCell represents another pioneering potential therapeutic that Living Cell has developed," Mr Yoshikawa said.

Living Cell was up 0.4 cents or 8.2 percent to 5.3 cents with one million shares traded.

ALLIED HEALTHCARE GROUP

Allied Health says it has raised $1.7 million in a placement at two cents a share and will offer a share purchase plan at the same price.

Allied said the funds would support the preparation of the Cardiocel heart patch prior to its launch, with marketing approval expected by July 2013 in at least one jurisdiction.

Allied said it had revenue forecast to be more than $7 million in the year to June 30, 2013 and approval of Cardiocel would be "a major inflection point".

The company said it expected to submit a 510k marketing application to the US Food and Drug Administration by April 2013.

Allied said that shareholders at the December 14 record date could subscribe for parcels of shares up to $15,000 and the offer would close on January 18, 2013.

The company said RBS Morgans was the lead manager for the placement and share plan.

Allied fell 0.3 cents or 12.5 cents to 2.1 cents with 5.7 million shares traded.

INVION (FORMERLY CBIO)

Invion says the US Food and Drug Administration has agreed to the proposed indication of systemic lupus erythematosus for INV103 formerly known as X-Toll.

Invion said that a pre-investigational new drug meeting with the Pulmonary, Allergy and Rheumatology Products Division of the FDA's Center for Drug Evaluation and Research confirmed that lupus was an important unmet medical need and accepted its clinical strategy, subject to the review of the final clinical trial protocol which would be provided in the investigational new drug submission

The company said that the FDA had accepted its animal and human safety data to support dosing in a proof-of-concept study in subjects with lupus.

Invion said it requested the FDA meeting for guidance on the clinical development path for INV103, a modified version of the naturally occurring human protein, chaperonin10.

The company said that stocks of INV103 had been transferred to Laureate Biopharmaceutical Services in Princeton, New Jersey, where they would be tested, formulated and filled for release to support a proof-of-concept clinical trial in lupus.

Invion chief executive officer Dr William Garner said the FDA meeting was "an important step in our clinical development plan for INV103".

"Our strategy to bring this drug into human clinical trials for patients suffering from lupus is now clear, and we aim to submit an IND early in 2013," Dr Garner said. "If granted this will be the second IND that Invion is working under to develop its assets."

Invion chief medical officer Dr Mitchell Glass said that INV103 was "a fascinating protein".

"We believe the clinical, safety and biological data obtained to date demonstrate characteristics which warrant investigation of this drug as a therapy for lupus and we are very pleased to have achieved clear FDA support for our plan as well as acceptance of our rationale for our strategies in chemistry, pharmacology, toxicology, and clinical development," Dr Glass said.

Last year as CBio, X-Toll failed to meet phase II endpoints for rheumatoid arthritis leading to a board spill and a merger with Inversion (BD: Aug 1, Nov 4, 2011; Aug 31, 2012).

Invion was up once cent or 21.3 percent to 5.7 cents.

IMMURON

Immuron says further studies in mice using its bovine colostrum product IMM-529 for Clostridium difficile infections support earlier preclinical results (BD: Sep 19, 2012).

Immuron said that IMM-529 was intended to prevent transmission and treat Clostridium difficile infection and the studies, with Monash University, validated the earlier results.

The company said that mice were infected with a lethal dose of Clostridium difficile and the mice that received IMM-529 survived infection and showed an increase in weight, while there was no survival for the control group that received a placebo treatment.

Immuron said that one arm of the study demonstrated a reduction in the number of spores found in the mice faeces, suggesting that transmission was also reduced.

The company said that since the infectious cycle and the type of disease seen in mice was similar to that seen in humans and it was known that the Clostridium difficile toxins caused the same effects in both species, the study model and the positive results supported its preparation for human trials.

Immuron said that Clostridium difficile caused diarrhoea, leading to colitis and other potentially life threatening intestinal conditions and there were no effective treatments.

Immuron said that optimization of the vaccine was continuing and would further enhance the product in preparation for human clinical trials expected in late 2013.

Immuron was unchanged at 0.8 cents.

ANTISENSE THERAPEUTICS

Antisense says the European Committee for Medicinal Products for Human Use has adopted a negative opinion for an Isis-developed second generation Antisense drug.

Antisense re-published a Sanofi Genzyme and Isis Pharmaceuticals announcement which said that the European Medicines Agency Committee had adopted a negative opinion for its marketing authorization application for Kynamro or mipomersen for the treatment of patients with homozygous familial hypercholesterolaemia.

Genzyme said it would request a re-examination by of the Committee opinion.

In October, Isis and its Australian licencing partner Antisense had significant price falls on concerns that the US Food and Drug Administration's Endocrinologic and Metabolic Drugs Advisory Committee might reject an application for Sanofi's Genzyme Kynamor (mipomersen sodium) to lower low-density lipoprotein cholesterol, due to liver toxicity issues (BD: Oct 17, 2012).

But the Committee voted nine-to-six that Genzyme had provided sufficient efficacy and safety data to support the marketing of Kynamro to lower low-density lipoprotein cholesterol in patients with homozygous familial hypercholesterolemia (BD: Oct 19, 2012).

A Genzyme media release said at that time that the FDA was not bound by the Committee's guidance, but would take its advice into consideration when reviewing investigational medicines.

Genzyme said it submitted the new drug application on March 29, 2012 and the FDA had set a target Prescription Drug User Fee Act (PDUFA) date of January 29, 2013.

Antisense managing director Mark Diamond told Biotech Daily in October that the drugs in his company's pipeline were "unique antisense sequences designed to block different RNA targets than Kynamro, [but] they are in the same class of second generation antisense drugs as Kynamro, that is, the same platform chemistry".

"In the three week dosing, multiple dose stage of the phase I clinical trial of ATL1103, there was one elevation in the liver enzyme ALT reported as an adverse event," Mr Diamond said (BD: Dec 7, 2011).

"Importantly, the ALT levels in this subject returned to normal during the dosing phase, suggesting no residual or cumulative effect of the drug on this safety parameter," Mr Diamond said.

In its media release today, Antisense said it was about to begin a phase II trial of ATL1103 for acromegaly designed to assess the drug's efficacy and safety at the doses to be investigated over an extended dosing period of three months.

The company said the trial would provide data on the drug's potential clinical advantages over existing pharmaceutical treatments for acromegaly including Somavert, presently regarded as the most efficacious drug on the market for the disease.

Antisense fell 0.1 cents or 7.7 percent to 1.2 cents with 12.2 million shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says its share plan has raised $1,163,442 before costs taking the total raised with its November placement to $13.2 million (BD: Nov 26, 2012).

Universal Biosensors said in November the funds from the placement and share plan at 90 cents a share would be used to accelerate new product development in patient self-test prothrombin time international normalized ration (PT-INR) blood coagulation test, immunoassay testing and molecular diagnostic testing and provide working capital to support new product launches and growth in manufacturing.

Universal Biosensors was up one cent or 1.1 percent to 91 cents.

CONSEGNA GROUP

Consegna said it had raised $500,000 through the placement of 125,000,000 shares at 0.4 cents each to sophisticated investors.
Consegna said that the funds would be used for working capital and to fund the launch of Breatheassist in 2013.
The company said it hoped to raise about $250,000 from a share purchase plan for investors at the record date of December 11, 2012, with shareholders would be able to buy shares in parcels to the value of $15,000.
Consegna was unchanged at 0.4 cents with 1.5 million shares traded.

AGENIX

Fortrend Small Cap Investors has become a substantial shareholder in Agenix with the acquisition of 3,603,218 shares or 9.1 percent.
The initial substantial shareholder notice said that the Collins Street Melbourne-based company acquired the shares “for and on behalf of BCB Management” with no further details.
Agenix was untraded at 3.8 cents.

CRYOSITE

Cryosite chairman Andrew Kroger increased his substantial shareholding in his company from 9,314,276 shares (19.97%) to 10,706,943 shares (22.96%).
The substantial shareholder notice said the 1,392,667 shares were acquired at 31 cents a share by Process Wastewater Technologies, of which Mr Kroger was the managing director.
Cryosite was up 3.5 cents or 11.1 percent to 35 cents.

ALCHEMIA

Alchemia has requested a voluntary suspension to follow the trading halt it requested on December 13, regarding the demerger of Audeo Oncology (BD: Dec 13, 2012).
Alchemia last traded at 55 cents.

STARPHARMA

Starpharma has appointed Eve Williamson as an additional vice-president of business development, from next year.
Starpharma said that Ms Williamson had worked in the pharmaceutical industry for more than 20 years including senior roles in business development, marketing and sales, pricing and reimbursement, and clinical research.
The company said that Ms Williamson had spent the last 12 years in business development and was responsible for the negotiation of more than 40 licence agreements with companies including Cephalon, Pfizer, Watson, Roche and Chugai.
Starpharma said that previously Ms Williamson had worked for Astra Zeneca, FH Faulding (Mayne, Hospira) and Phebra.
The company said Ms Williamson held a post-graduate diploma in business from the University of Melbourne.
Starpharma fell half a cent or 0.4 percent to $1.135.

THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says structural biologist Prof Peter Colman has won the inaugural Society of Crystallographers in Australia and New Zealand Bragg medal.

The Institute said the medal recognized Prof Colman's scientific career of more than 40 years, using X-rays to determine the structures of proteins.

WEHI said the award was presented at a symposium in Adelaide marking the centenary of the discovery of X-ray crystallography by Australian-born physicist William Lawrence Bragg who won the 1915 Nobel Prize in Physics with his father and collaborator, William Henry Bragg, for the discovery.

The Institute said that Prof Colman had made many important discoveries about how proteins functioned by determining their molecular structure.

WEHI said that while working at the Commonwealth Scientific and Industrial Research Organisation in the 1980s, Prof Colman and colleagues used X-ray crystallography to discover the three-dimensional molecular structure of the influenza virus protein neuraminidase, which led to the development of Biota's anti-influenza medication, Relenza, one of the first times a medication had been designed directly from a protein structure.

WEHI said that since 2001, Prof Colman had worked at the Institute and was focusing on determining the structures of the Bcl-2 family of proteins that control whether cells survive or die and were known to be important in cancer cell development and resistance to anti-cancer agents.

The institute said that insights into the structure of these proteins, including discoveries made by Prof Colman and his colleagues, had led to the design of a new class of potential anti-cancer agents, currently in clinical trials.