Biotech Daily

Thursday July 14, 2011

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: SUNSHINE HEART UP 8%; LBT DOWN 18%**

*** TISSUE THERAPIES' VITROGRO IMPROVES 22 OF 24 VENOUS ULCERS**

*** UQ TO OPTIMIZE ENGENEIC'S MINICELL DELIVERY SYSTEM**

*** GENETIC TECHNOLOGIES TAKES FUNDING HALT TO SUSPENSION**

*** CATHRX APPLIES FOR CE MARK FOR VARIABLE LOOP CATHETER**

*** PRANA TO ISSUE UP TO 5m US SHARES**

*** HEALTHLINX ENDS SPRINGTREE NOTE; OVPLEX VALUED AT $105m**

*** AVEXA HAS 17% OF ALLIED HEALTH**

MARKET REPORT

The Australian stock market fell 0.53 percent on Thursday July 14, 2011 with the S&P ASX 200 down 24.1 points to 4490.7 points.

Eleven of the Biotech Daily Top 40 stocks were up, 15 fell, four traded unchanged and 10 were untraded.

Sunshine Heart was best, up 0.4 cents or 7.8 percent to 5.5 cents with 115,000 shares traded, followed by Impedimed up 3.5 cents or 5.5 percent to 67 cents with 26,598 shares traded and Tissue Therapies up 4.4 percent to 59 cents with 996,468 shares traded.

Circadian and Phosphagenics climbed more than three percent; Bionomics, Clinuvel and Optiscan rose more than two percent; with Anteo and Sirtex up more than one percent.

LBT led the falls for the second day in a row, down one cent or 18.2 percent to 4.5 cents with 65,000 shares traded.

Alchemia and Starpharma lost more than six percent; Prana, Prima and QRX fell five percent or more; Cellmid and Phylogica were down more than four percent; Nanosonics and Universal Biosensors lost three percent; with Biota, Cochlear, Pharmaxis and Viralytics down more than one percent.

TISSUE THERAPIES

Tissue Therapies says its Cardiff and Australian trial of Vitrogro for venous ulcers has shown reductions in wound size for 22 of 24 patients at 12 weeks post-treatment.

Tissue Therapies chief executive officer Dr Steven Mercer told Biotech Daily that of the 24 evaluable patients eight had complete healing and two more had 98 percent healing of wounds that were up to 11 years old and had not been treatable with other forms of care.

Dr Mercer said that one patient described as unchanged had his venous ulcer for 30 years and while the area remained unchanged there was a visible decrease of 2mm in the depth of the wound, which also showed other signs of healing.

Dr Mercer said the trial, at two centres in Cardiff, Wales as well as Freemantle, Western Australia and two centres in Brisbane, recruited a total of 53 patients.

He said 10 patients were not evaluated with four excluded from the data analysis due to active wound infection or significant medical complications unrelated to Vitrogro and six patients withdrawn from the study due to medical problems unrelated to Vitrogro, or lost to follow up.

Dr Mercer said 19 patients were currently receiving treatment.

“These results are consistent with and reinforce the earlier clinical data,” Dr Mercer said. “Vitrogro assists these patients in a way they haven’t had before and it positions us well for a commercial partnership later this year and sales in the EU by the end of June 2012,” Dr Mercer said.

Tissue Therapies said that the multi-centre international wound healing study was led by Cardiff University Wound Healing Clinic’s Prof Keith Harding and Dr Girish Patel.

The company said the average reduction in wound size was 65 percent with a median of 72 percent after 12 weeks of treatment and ”a number of patients” reported a reduction in pain with the treatment.

Tissue Therapies said that the average time venous ulcers had not responded to expert care before Vitrogro treatment was 37 months with a median of 10 months.

The company said the average age of patients that have completed treatment so far is 71 years with a median of 73 years.

Tissue Therapies said the EU clinical study was evaluating weekly or twice weekly Vitrogro treatment of venous leg ulcer patients who have not responded to compression therapy, the current standard of care for at least four weeks, many for much longer.

The company said 28 patients had completed the study to date, with no adverse events related to Vitrogro reported

Tissue therapies said it expected the completion of the data analysis for all patients by the end of September 2011 and the final report to be submitted as part of the EU approval filing planned for later this year.

Dr Mercer said that with data from a total of 58 venous ulcer patients from three clinical trials, “I am very confident that we will have the data necessary for a successful submission for EU approval for sale, on time and as planned later this year when final manufacturing stability data is available”.

The preliminary data confirmed the results of the earlier Australian and Canadian human trials by showing that Vitrogro restarts or accelerates healing of chronic venous ulcers that don’t respond to expert care, with reduction of ulcer size as well as improved wound characteristics and pain reduction.

“Unlike our previous studies these patients typically have a considerable history of recurrent ulceration and have complicated wounds that would not be expected to heal,” Dr Mercer said. “They also have co-existing conditions in addition to the underlying disease in their arteries or veins, which together make this study a more challenging test.”

Tissue Therapies was up 2.5 cents or 4.4 percent to 59 cents.

ENGENEIC

Engeneic says a $352,000 Australian Research Council grant will fund the optimization of its minicell based drug delivery system in conjunction with the University of Queensland.
The Sydney-based company said the Engeneic delivery vehicle (EDV) technology was based on bacterially-derived minicells which could be loaded with existing chemotherapies or newer forms of drugs.
Engeneic said the minicells could load many times the drug concentration of other delivery technologies and using antibodies attached to the outside of the minicell they can be targeted to deliver the loaded drug directly to tumor cells.
The company said in a media release that the technology 'supercharged' the targeting antibodies, giving them the ability to deliver a proven chemotherapeutic payload without the toxic side effects associated with cancer treatment.
Engeneic said its EDVs were "proven to carry a therapeutically significant payload of many types of anticancer molecules" including generic drugs such as paclitaxel, newer small molecule drugs and small interfering RNAs (siRNAs).
Engeneic said it had shown that minicell-delivered siRNAs targeted to tumor cells could reverse drug resistance in mice carrying human tumors in an article entitled 'Sequential treatment of drug-resistant tumors with targeted minicells containing siRNA or a cytotoxic drug' published in Nature Biotechnology.
An abstract is at http://www.nature.com/nbt/journal/v27/n7/abs/nbt.1547.html.
Engeneic said the ARC linkage grant with the Australian Institute for Bioengineering and Nanotechnology at the University of Queensland would allow the identification of receptors on cancer cells and development of antibodies to target them.
The company said the antibody-targeted EDVs delivered cancer therapies directly into cancerous cells, resulting in high drug concentrations within the targeted cells while reducing systemic side effects.
Engeneic co-founder and managing director Dr Jennifer MacDiarmid said the company was "playing the rogue cells at their own game".
"They switch on the gene to produce the protein to resist drugs and we are switching off the gene, which in turn makes the cancer cell sensitive to the drug again," Dr MacDiarmid said.
Engeneic said the bacterial origins of the minicell made scaling-up production of the delivery vehicles easy and cost effective.
Co-founder and managing director Dr Himanshu Brahmbhatt said the methodology "does not damage the normal cells and is applicable to a broad spectrum of solid cancers".
"This technology will also potentially open the door to tailor made medicine where EDVs carrying different payloads can be mixed and matched to the individual's cancer," Dr Brahmbhatt said.
Engeneic said it was carrying out a first-in-man phase I safety trial.
Engeneic is a private company.

GENETIC TECHNOLOGIES

Genetic Technologies has requested a voluntary suspension to follow the trading halt it requested on July 12, 2011, pending an announcement "to consider a proposed capital raising".
Genetic Technologies had $7.2 million in cash at March 31, 2011, with revenue of $2,024,729 for the three months.
Genetic Technologies last traded at 32.5 cents.

CATHRX

Cathrx says it has submitted an application for Conformité Européenne (CE) mark of its Variable Loop Catheter.

Cathrx said the catheter was designed for the treatment of atrial fibrillation and would be the first catheter in its second generation device range.

Cathrx chief executive officer Jeff Goodman said the second generation platform was designed to maximize re-manufacturability.

“The Variable Loop Catheter is our first device to utilize this new platform and will be followed by a therapeutic and/or ablation device,” Mr Goodman said.

Cathrx was untraded at 15 cents.

PRANA BIOTECHNOLOGY

Prana has filed a prospectus supplement to sell up to 50,000,000 shares, as 5,000,000 American depositary shares (ADSs) through an at-the-market offer.

Prana chairman Geoffrey Kempler told Biotech Daily that the mechanism would allow the company to sell Nasdaq secondary-listing shares as required to raise funds.

In a media release Prana said the American depositary shares would be offered through McNicoll, Lewis & Vlak which would sell them at market prices from time to time, including sales by brokers' transactions on the Nasdaq Capital Market, at Prana's discretion and instruction.

Prana said it intended to use the proceeds for ongoing and future research programs into the development of its compounds, including lead compound PBT2 for Alzheimer’s disease and for working capital purposes.

Prana said it intended to begin a phase II imaging trial for PBT2 in Alzheimer’s disease patients and a phase II trial for PBT2 in Huntington’s disease patients later this year.

Prana fell one cent or 5.6 percent to 17 cents.

HEALTHLINX

Healthlinx says it has terminated its convertible loan agreement with Springtree Special Opportunities Fund.

Healthlinx said the $7.23 million draw-down equity facility was approved by shareholders in 2009 and had been terminated “by mutual consent effective immediately” (BD: Oct 5, Nov 26, 2009).

Separately, Healthlinx issued a media release saying it’s Ovplex ovarian cancer diagnostic’s intellectual property had been valued by Acuity Technology Management of Suite 329, 1 Queens Road, Melbourne at about $105 million.

In June, Healthlinx announced a share plan at between 3.25 cents and 3.5 cents a share, but on the day of the announcement fell to three cents a share. (BD: Jun 22, 2011).

On June 30, Healthlinx said it had a $3 million draw down equity facility with an unnamed US institutional investor.

Healthlinx climbed as much as 73.1 percent to 4.5 cents from 2.6 cents, before closing up 1.2 cents or 46.15 percent at 3.8 cents with 13.8 million shares traded.

AVEXA, ALLIED HEALTH

Avexa says it holds 96,000,000 Allied Health shares or 16.9 percent of the company.
Avexa filed the initial substantial shareholder notice following the completion of the transfer of shares and convertible notes, following the Allied takeover of Biomd.
Avexa was unchanged at 4.8 cents.
Allied Health fell 1.5 cents or 20 percent to six cents with 2.7 million shares traded.