Biotech Daily

Thursday August 23, 2012

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH FLAT: PHYLOGICA UP 12.5%, UNIVERSAL BIO DOWN 10%**

*** MIREVEN, SILENCE COLLABORATE ON WAIMR'S miRNA FOR CANCER**

*** US FDA CONDITIONAL APPROVAL FOR GI DYNAMICS PIVOTAL TRIAL**

*** SENZ CLAIMS FUNDING FOR VAL-1000 LEUKAEMIA TRIALS**

*** MEDICAL DEVELOPMENTS REVENUE UP 11%, PROFIT UP 55%, DIVIDENDS**

*** CRYOSITE REVENUE UP 20% to $8m, PROFIT UP 206% TO $1m**

*** ITL REVENUE DOWN 25% TO $31m, PROFIT UP 41% to $1.3m**

MARKET REPORT

The Australian stock market edged back 0.18 percent on Thursday August 23, 2012 with the S&P ASX 200 up 7.7 points to 4,383.7 points.

Twelve of the Biotech Daily Top 40 stocks were up, 12 fell, 13 traded unchanged and three were untraded.

Phylogica was the best, up 0.3 cents or 12.5 percent to 2.7 cents with 2.9 million shares traded.

Allied Health climbed 8.7 percent; both Benitec and Cellmid were up 6.25 percent; Circadian and Ellex were up more than five percent; Phosphagenics was up 3.85 percent; Psivida rose 2.9 percent; QRX was up 1.4 percent; with Acrux, Cochlear, Sirtex and Starpharma up by less than one percent.

Universal Biosensors led the falls, down seven cents or 10.2 percent to 61.5 cents with 55,566 shares traded.

Antisense and Sunshine Heart lost more than five percent; Neuren and Patrys both fell 4.2 percent; Biota, Mesoblast, Prana and Tissue Therapies shed more than two percent; with Heartware, Pharmaxis, Resmed and Viralytics down by less than one percent.

MIREVEN PTY LTD, WESTERN AUSTRALIAN INSTITUTE FOR MEDICAL RESEARCH

Mireven has contracted London's Silence Therapeutics PLC to assess the delivery potential of Silence's delivery systems with its micro-RNA (miRNA) therapeutics.

Mireven was created in 2010 through an investment from the Brandon Capital managed Medical Research Commercialisation Fund to commercialize work on the anti-cancer potential of micro-RNA-7 (miR-7) by the Western Australian Institute for Medical Research's Prof Peter Leedman and Dr Keith Giles.

Brandon Capital partner and Mireven director Dr Stephen Thompson told Biotech Daily that the value of the initial contract with Silence was undisclosed and Mireven was looking at a range of delivery systems.

"We are paying them to see if their delivery system can deliver out compounds for treatment of a range of cancers," Dr Thompson said.

"If this work is successful we would continue to work with Silence," Dr Thompson said.

Dr Thompson said the work was expected to take about one year.

A media release from Silence said that WAIMR's published research showed that miR-7 could knock-out an essential growth receptor for cancer, known as the epidermal growth factor receptor (EGFR), with the additional potential to inhibit multiple EGFR signaling pathways that promote cancer development.

Silence said that EGFR was a major target for cancer therapy because it was often associated with disease progression, resistance to chemotherapy and radiation therapy.

Silence said that under the agreement with Mireven it would formulate a miR-7 mimetic with its three proprietary delivery systems to evaluate miR-7 in various cancer models.

Silence said it would undertake in vitro and in vivo studies of the formulated miR-7.

Silence said that its most advanced lipid delivery technology, Atuplex, had demonstrated broad systemic delivery to the vascular endothelium and was used in ATU027, its lead oncology candidate, in phase I trials.

Other closely related delivery systems included a novel lipid delivery system that enabled functional, highly specific and efficient delivery of RNAi therapeutics to the pulmonary vascular endothelium and one that was a novel lipid-based formulation that functionally delivered small interfering RNA (siRNA) to liver endothelial cells, hepatocytes and other liver cell types with high efficiency.

Silence chief scientific officer Dr Klaus Giese said the Mireven collaboration was "the fourth collaboration that we have recently signed to explore the use of Silence's delivery technologies for micro-RNAs".

"Whilst we remain internally focused on the delivery of our siRNA therapies, we continue to broaden the potential value of our proprietary delivery systems by collaborating with partners," Dr Giese said.

"Functional delivery to target cells is widely recognized as one of the greatest challenges facing most nucleic acid therapies," Dr Giese said.

"Our three proprietary RNAi delivery systems, Atuplex, DACC and DBTC, deliver effective doses of RNAi to key intracellular targets in vascular endothelium, lung and liver respectively, and provide our partners with a growing range of solutions to overcome their delivery challenges," Dr Giese said.

Dr Thompson said that Mireven's founding scientists "have developed a compelling body of preclinical data supporting the potential of miR-7 to suppress tumor growth, particularly in the many cancers known to be controlled by the EGF receptor signaling pathway including glioblastoma".

"Mireven is currently testing drug-like versions of miR-7 in key models of human cancer," Dr Thompson said.

GI DYNAMICS

GI Dynamics says it has conditional US Food and Drug Administration approval for a pivotal trial of the Endobarrier for obese patients with uncontrolled type 2 diabetes.
GI Dynamics said the conditional approval indicated the FDA agreed with the overall trial design and while “minor details” were being finalized allowed the company to move to the institutional review board approval process required prior to enrolling patients.
The company said the 500-patient pivotal trial would be a randomized, multi-center, double-blind, “sham-controlled” trial at 25 sites in the US, expected to begin this year.
The controls will undergo the procedure but not receive any device.
GI Dynamics said the trial was designed to assess improvements in diabetes over a treatment period of up to 12 months.
The company said that the primary endpoint was improvement in HbA1c, a key blood sugar measure for diabetes, with secondary measures including weight loss and improvements in cardiovascular risk factors, such as cholesterol.
GI Dynamics chief executive officer Stuart Randle said the company was “very pleased that the [FDA] has chosen to recognize the substantial amount of scientifically sound data generated from our clinical trials conducted outside the United States, allowing us to move directly into a pivotal trial”.
“Going directly into a pivotal trial eliminates the need for a pilot trial and has the potential to accelerate commercialization of the Endobarrier in the US,” Mr Randle said.
The company said the Endobarrier was in Chile, Australia and some European countries.
GI Dynamics fell four cents or 4.7 percent to 81 cents.

SENZ ONCOLOGY

Senz Oncology says seed funding from Covalence Inc will cover early clinical trials of VAL-1000 for leukemia, in collaboration with California’s Allyence Research Inc.
Senz co-founder and executive director Dr Anthony Filippis told Biotech Daily he could not disclose the value of the funding but said it would cover the cost of three phase I/II trials of up to a total of 60 patients with acute leukaemia.
Dr Filippis said that VAL-1000 was a small molecule, oral chemotherapeutic agent with low toxicity, a potentially novel mechanism of action, targeting several cellular kinases including cyclin-dependent kinase, involved in the cell division mitosis.
Dr Filippis said VAL-1000 had a significant history of use in humans and had been in phase I safety trials, but was unable to provide any details.
In a media release, Senz said it was established by Afandin’s Dr Ian Nisbet and Dr Filippis to develop new cancer drugs.
Senz said that both Covalence and Allyence were based in Menlo Park, California and Allyence was a private company, with Matrix Pharmaceuticals and Chemgenex Therapeutics founder Dr Dennis Brown its president.
The media release said VAL-1000 had potential; for the treatment of acute leukemias, including acute myeloid leukemia, having demonstrated significant activity in cell lines and primary tumors, representing a range of disease genotypes.
Senz said it would provide new treatment options for cancer patients, “leveraging the benefits of the Australian regulatory and taxation environment to provide time and cost effective drug development”.
Dr Brown said Australia’s research and development tax credit and clinical trial notification scheme “were critical elements in the decision to co-develop VAL-1000 with Senz”.
Senz said that Dr Brown had been appointed a non-executive director.
Senz is a private company.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says that total revenue for the 12 months to June 30, 2012 was up 10.9 percent to $11,313,000 with net profit after tax up 55.1 percent to $2,704,024.
Medical Developments said that overall sales were up 11 percent, with medical device sales up 24 percent, asthma device sales up 247 percent and a 20 percent increase in its Penthrox methoxyflurane analgesic inhaler sales for the 12 months to June 30, 2012.
Medical Developments chairman David Williams told Biotech Daily that the company had paid two fully-franked three cents dividends in year to June 30, 2012 and would pay shareholders on the record date of September 5, 2012 a further three cent dividend on October 10, 2012.
The company said that net tangible asset backing per share was down 12.1 percent to 8.0 cents and basic earnings per share was up 50 percent to 5.1 cents for the year to June 30, 2012 compared to 3.4 cents for the previous corresponding period.
Medical Developments said it had $3,483,000 in cash and cash equivalents at June 30, 2012, compared to $3,541,000 at the end of the previous financial year.
Medical Developments was unchanged at $1.15.

CRYOSITE

Cryosite says that revenue for the 12 months to June 30, 2012 was up 20.4 percent to $8,021,096 with net profit after tax up 205.8 percent to $1,022,479.
Cryosite said revenue came from both its ongoing cord-blood banking service and the recently established clinical trials logistics business.
Cryosite said a maiden unfranked dividend of 0.5 cents a share was paid during the year.
The company said that net tangible asset backing per share was up 15.8 percent to 11.7 cents and diluted earnings per share was up 210 percent to 2.17 cents for the year to June 30, 2012 compared to 0.7 cents for the previous corresponding period.
Cryosite said it had $4,524,750 in cash and cash equivalents at June 30, 2012, compared to $2,910,943 at the end of the previous financial year.
Cryosite fell four cents or 13.3 percent to 26 cents.

ITL

ITL says revenue from ordinary activities for the 12 months to June 30, 2012 was down 25 percent to $30,612,000 with a net profit after tax up 41 percent to $1,323,000.
ITL company secretary Trevor Doolan told Biotech Daily that the company needed to publish data for both ordinary activities and continuing operations following the sale of its SEA Malaysia business on January 1, 2012, and a restructure as well as a change from sales-based revenue to commission-based revenue.
ITL said net tangible assets per share at June 30, 2012 was up 4.4 percent to 11.9 cents and diluted earnings per share was up 49.3 percent to 1.06 cents, compared to the previous year's 0.71 cents.
The company said it held $1,007,000 in cash and cash equivalents at June 30, 2012, compared to $2,457,000 at June 30, 2011.
ITL was up one cent or five percent to 21 cents.