



Biotech Daily

Tuesday August 7, 2012

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: SUNSHINE HEART UP 15%, ANTISENSE DOWN 12%**
- * **COCHLEAR REVENUE DOWN 4% TO \$779m, PROFIT DOWN 68% to \$57m**
- * **UNIVERSAL BIOSENSORS H1 REVENUE UP 133% TO \$6m, LOSS DOWN 57%**
- * **YALE NEW HAVEN BUYS COMPUMEDICS' NEUVO FOR EPILEPSY**
- * **ACRF FUNDS TWO NEW WEHI CANCER LABS**
- * **ANTISENSE PREPARES FOR PHASE II ATL 1103 ACROMEGALY TRIAL**
- * **STARPHARMA, NUFARM EXPAND DENDRIMERS FOR CROPS**
- * **CORRECTION: MEDICAL DEVELOPMENTS**
- * **KEY US PATENT FOR CALZADA POLYNOVO BIODEGRADABLE POLYMERS**
- * **BONE: AXCESS DIABETES LICENCE 'DEMONSTRATES CONFIDENCE'**
- * **HUNTER HALL REDUCES TO 27% IN SIRTEX**
- * **WILSON HTM REDUCES BELOW 5% IN AVITA**

MARKET REPORT

The Australian stock market was up 0.44 percent on Tuesday August 7, 2012 with the S&P ASX 200 up 19.0 points to 4,291.6 points. Fifteen of the Biotech Daily Top 40 stocks were up, 10 fell, eight traded unchanged and seven were untraded. The Big Caps fell.

Sunshine Heart was the best, up 0.6 cents or 14.6 percent to 4.7 cents with 195,000 shares traded.

Optiscan climbed 6.7 percent; Allied Health was up 5.6 percent; Avita, Phylogica, Prana, Starpharma and Sirtex were up more than three percent; Genera and Impedimed rose more than two percent; with Acrux, Alchemia and Viralytics up more than one percent.

Antisense led the falls, down 0.2 cents or 11.8 percent to 1.5 cents with 26.6 million shares traded. Cochlear, Patrys and Psivida lost five percent or more; Prima fell four percent; Bionomics, Heartware and Tissue Therapies were down more than three percent; Nanosonics and Pharmaxis shed two percent or more; with Anteo and CSL down more than one percent.

COCHLEAR

Cochlear says revenue for the 12 months to June 30, 2012 was down four percent to \$778,996,000 with a net profit after tax down 68 percent to \$56,803,000.

Cochlear chief executive officer Dr Chris Roberts told a teleconference that following the recall of the Nucleus 500 series implant and the re-entry of competitor Advanced Bionics, the company had lost about five percent of market share to 65 to 70 percent.

Last year, Cochlear recalled its Nucleus C-500 implant, later attributing the cause of the failure to the brazing process during manufacturing (BD: Sep 12, Dec 20, 2011).

Today, Dr Roberts again paid tribute to the flexibility of the staff and manufacturing process that the company was able to swap back to the earlier CI-24RE model, which had equivalent performance to the Nucleus CI-500.

Dr Roberts said that although revenue fell four percent to \$779 million, in constant currency terms revenue was up one percent and while no-one wanted to see a fall in profit, the company increased its full-year dividend by nine percent to \$2.45 per share.

Dr Roberts said the company would bring the CI-500 back to the market but declined to provide a timeline "for competition reasons".

Dr Roberts said the fall in profit was not solely attributable to the recall, with timing issues for the previous model a factor in China, along with a lack of stock in the delivery pipeline.

Dr Roberts said the company was "well-progressed" in seeking regulatory approval for the CI-500 but an application had not yet been filed.

He said the company was working on other products as well as the return of the CI-500.

Dr Roberts said that expenditure on research and development was up 10 percent.

Cochlear said net tangible assets per share at June 30, 2012 was down 40 percent to 313.0 cents and diluted earnings per share was down 68.4 percent to 99.8 cents, compared to the previous year's 316.1 cents.

The company said it held \$68,486,000 in cash and cash equivalents at June 30, 2012, compared to \$72,423,000 at June 30, 2011.

Cochlear fell \$3.40 or 5.1 percent to \$63.00 with 351,300 shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says revenue for the six months to June 30, 2012 was up 133 percent to \$14,719,377, with a net loss after tax down 57.0 percent to \$3,494,297.

Universal Biosensors said that revenue from the sale of Onetouch Verio strips by Johnson & Johnson's Lifescan was up 402 percent from about \$200,000 to \$US985,242.

Universal Biosensors chief executive officer Paul Wright told a teleconference that the service fee was one US cent per strip and allowed Biotech Daily to draw the conclusion that 98,524,200 strips had been sold.

Mr Wright said that separate from the service fee, the company received \$9.5 million for the manufacturing of the strips and about \$4.2 million for research and development milestones from Lifescan and Siemens.

Mr Wright said the company was in transition "from a business focused on research and development to a revenue generating enterprise".

The company said its net tangible assets per share fell 20.0 percent to 20 cents and diluted loss per share fell 60.0 percent from five cents to 2.0 cents.

The company said its cash burn decreased from \$5.8 million for the six months to June 30, 2011 to \$400,000 for the six months to June 30, 2012.

Universal Biosensors said it had cash at June 30, 2012 of \$14,709,678 compared to \$17,487,750 at June 30, 2011.

Universal Biosensors was unchanged at 60 cents.

COMPUMEDICS

Compumedics says Yale New Haven Medical Center brain scans using its Neuvo long-term electroencephalography is a major enhancement for epilepsy patients.

Compumedics said that Yale, using its Neuvo long-term electroencephalography (LTEM) with about 300 electrodes on the brain cortex had created “a major enhancement in the diagnostic capabilities for evaluating patients requiring surgical correction for epilepsy”. The company said that higher quality brain recordings and more precise brain analysis could improve patient outcomes.

Compumedics US vice-president of marketing Jeff Kuznia said the “high-channel count recording is the first to demonstrate the real value of this exclusive technology in the management of a patient with epilepsy”.

“The technical advantages of Compumedics' integrated solution will be difficult for our competitors to match any time soon,” Mr Kuznia said.

Compumedics said the breakthrough provided “a firm leading technology entry into the \$250 million per annum global neurology monitoring market”.

The company said there were estimates that more than three million people in the US were affected by epilepsy with 200,000 new cases each year, of which 10 percent could require surgical brain resections to control debilitating seizure activity.

Compumedics said there were more than 70 dedicated epilepsy centers in the US that provided advanced diagnostic and treatment services for epilepsy and many more hospitals that offer more limited epilepsy management services.

The company said that the epilepsy centers indirectly influenced future purchasing decisions at the approximate 6,000 hospitals across the US, which perform either routine long-term electroencephalography or other neurological diagnostics and monitoring.

Compumedics said that during the past 12 months, it had installed its neurological monitoring systems at five centers, including Yale, with each installation representing \$500,000 to \$1.5 million in revenue.

The company said that the Yale New Haven Medical Center had one Neuvo LTM EEG system capable of recording up to 512 individual channels of high-density EEG data on a single patient for days or weeks at a time.

Compumedics said that two additional Neuvo systems would be installed in the next few months and the Center used its Neuroscan Curry software to integrate brain imaging from patients' magnetic resonance imaging and computed tomography scans with the EEG recordings, helping identify the source of epileptic seizures in preparation for surgical intervention.

The company said that Yale and other institutions chose its products ahead of the competition as it was the highest density and signal quality brain monitoring system in the market.

Compumedics said the combination of the Neuvo LTM EEG system and the Curry neuro-imaging analysis software made it easier for epileptologists and neurosurgeons to identify which specific regions in the brain were most likely to be the cause of severe seizure activity in an afflicted patient.

Compumedics chairman Dr David Burton said the company's “renewed focus on the neuro-diagnostics market in the US, with the recent expansion of our sales force and increased marketing efforts are producing positive results and we foresee continued growth in this important segment of our business”.

“This US long-term EEG monitoring milestone complements the recent successes we have had in the European and Asian neuroscience markets,” Dr Burton said.

Compumedics was untraded at 7.5 cents.

THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says Melbourne Lord Mayor Robert Doyle officially opened two new cancer research laboratories at the Institute.

The Institute said that the laboratories for its stem cells and cancer division and chemical biology division were established with the assistance of a \$2 million grant from the Australian Cancer Research Foundation and would expand research programs into the causes of, and new treatments for, some of the most prevalent cancers in Australia, including breast cancer, ovarian cancer, lung cancer and leukaemia.

The Walter and Eliza Hall Institute said the stem cells and cancer division would study the biology of epithelial cancers, including breast, lung and ovarian cancer, which accounted for about 80 percent of human cancers.

The head of the chemical biology division Prof David Huang said the new facilities would enable institute researchers to develop new medications for cancers.

WEHI director Prof Doug Hilton said the fit-out of the new cancer laboratories would provide an important boost to the institute's cancer research programs.

ANTISENSE THERAPEUTICS

Antisense says start up activities have begun for its European trial of growth hormone receptor targeting drug ATL1103 phase II trial in patients with acromegaly.

Antisense said that UK Christie NHS Foundation Trust's Prof Peter Trainer had been appointed chief investigator, the trial protocol had been finalized and the UK-based Orion Clinical Services had been appointed to conduct the trial.

The company said the 24-patient trial would be a randomized, open-label, parallel group study of the safety, tolerability, pharmacokinetics and efficacy of two subcutaneous dosing regimens of ATL1103 in adult patients with acromegaly dosed for 13 weeks.

Antisense said the primary endpoints were to evaluate the safety and tolerability and evaluate the single dose and multiple dose pharmacokinetic profiles of ATL1103 via the subcutaneous route in patients with acromegaly.

The company said that a secondary endpoint was the evaluation of ATL1103's effect on serum insulin like growth factor-I (IGF-I) levels in patients.

Antisense said a reduction of elevated levels of serum IGF-I to normal was the therapeutic endpoint in treatment, and reducing the effects of growth hormone and IGF-I action had a potential role in the treatment of diabetic retinopathy, nephropathy and cancer.

The company said it expected the first patient to be dosed by the end of this year, with the results of ATL1103's effects on serum IGF-I levels expected by the end of 2013 and a final report expected by April 2014.

Antisense fell 0.2 cents or 11.8 percent to 1.5 cents with 26.6 million shares traded.

STARPHARMA HOLDINGS

Starpharma says Nufarm will use its Priostar dendrimer technology to develop crop protection formulations, but the terms of the agreement were not disclosed.

Nufarm Australia general manager Lachlan McKinnon said the collaboration with Starpharma reflected his company's "renewed emphasis on technological innovation".

Starpharma said that the Priostar dendrimer technology had wide applicability in the agricultural chemical sector including more concentrated formulations to reduce transport costs, reduction in solvent loading, improved activity and increased adhesion, to reduce losses due to rain run-off and the need for multiple applications.

Starpharma was up 4.5 cents or 3.15 percent to \$1.475.

CORRECTION: MEDICAL DEVELOPMENTS INTERNATIONAL

Last night's edition reported Medical Developments chief executive officer John Sharman saying the company expected to finalize the European application "by October 2013". In the company's media release, Mr Sharman said he expected to finalize the application "sometime in Q3FY2013" and has subsequently told Biotech Daily he meant "by March 2013, not October 2013".

Biotech Daily apologizes unreservedly for the error and has awarded the sub-editor a Silver Medal for the effort.

Biotech Daily notes that many countries and some Australian companies do not use the period from July 1 to June 30 as the financial year.

We would implore companies to set specific months rather than ambiguous quarters-of-a-year for milestones and timelines.

Medical Developments was up 10 cents or 10.5 percent to \$1.05.

CALZADA, POLYNOVO BIOMATERIALS

Calzada says the US Patent and Trademark Office has allowed wholly-owned subsidiary Polynovo's seminal patent entitled 'Biodegradable Polyurethane/Urea Compositions'.

Calzada said that the patent was "one of the most significant in Polynovo's portfolio" covering a broad range of biodegradable polymer compositions, including thermoplastics and thermosets, as well as a number of method claims.

The company said that the materials covered by the patent included, in-situ cured bone void fillers and fracture fixation products.

Calzada said the original Australian was filed July 23, 2002 and the patent term adjustment extended the term to 2026.

Calzada was up 0.4 cents or 8.9 percent to 4.9 cents.

BONE MEDICAL

Bone says related company Proxima Concepts has its first partnering agreement for the Axxess oral peptide formulation to be used for diabetes.

Bone said it licenced the Axxess technology from Proxima for its Capsitonin oral calcitonin compound and Capthymone, its oral parathyroid hormone compound.

Bone chairman, chief scientific officer and Axxess inventor Dr Roger New is also the chairman of Proxima Concepts.

The company said the new licence was acquired by the Jersey, Channel Islands Diabetology with India's USV and announced on July 31, 2012.

Bone said that Diabetology would use the Axxess technology to develop an oral insulin product for diabetes.

The company said it was not involved in the agreement which covered the development and commercialization of Diabetology's oral insulin product in India.

Dr New said the deal was important to Bone's work on musculoskeletal diseases because it was "a demonstration of confidence in the Axxess system by a leading pharmaceutical company in one of the world's most important emerging markets and a signpost for the partnering potential for Bone Medical in its own target fields of therapy".

"Peptide-based therapeutics are some of the most successful medical advances in the treatment of diseases like these, yet none of them have yet been successfully developed for oral delivery," Dr New said.

Bone was unchanged at 0.4 cents with 18.5 million shares traded.

SIRTEX MEDICAL

Hunter Hall Investment Management has reduced its substantial holding in Sirtex from 15,537,884 shares (27.86%) to 14,979,180 shares (26.86%).

Hunter Hall said that it bought and sold shares at a range of prices between December 19, 2011 and August 6, 2012.

Sirtex was up 27 cents or 3.8 percent to \$7.35.

AVITA MEDICAL

Wilson HTM Investment Group has ceased its substantial holding in Avita from 13,241,000 shares (5.56%) to 11,237,937 shares (4.72%).

In December 2011, Wilson HTM Investment Group reduced its substantial holding in Avita from 16,959,950 shares (7.12%) to 13,241,000 shares (5.56%), selling the 3,718,950 shares for \$388,711 or an average price of 10.45 cents a share (BD: Dec 6, 2011).

Today, Wilson HTM said that between January 31 and August 8, 2012, the Wilson HTM Priority Core Fund and "individually managed accounts" sold 2,003,063 shares for \$393,886 or an average price of 19.7 cents a share.

Avita was up half a cent or 3.2 percent to 16 cents.