



Biotech Daily

Friday September 13, 2013

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: ATCOR UP 14%; COMPUMEDICS DOWN 13%**
- * **SUNSHINE HEART PIVOTAL TRIAL ENROLS 1st OF 388 PATIENTS**
- * **PRANA PBT2 HUNTINGTON'S RESULTS DELAY, ALZHEIMER'S EXTENDED**
- * **ONCOSIL \$7.8m PLACEMENT, PLAN FOR \$2.5m MORE, DIRECTOR, CO SEC**
- * **ACTINOGEN CLOSES LABORATORY, LOSES STAFF**
- * **COCHLEAR 2nd STRIKE SPILL, \$1.4m CEO OPTIONS AGM**
- * **CSL AGM FOR 25,000 CEO PAUL PERREAULT 'RIGHTS', DR MCNAMEE \$5m**
- * **BENITEC LUNG CANCER CANDIDATE WINS UNI OF NSW GONG**

MARKET REPORT

The Australian stock market fell 0.44 percent on Friday September 13, 2013 with the S&P ASX 200 down 22.9 points to 5,219.6 points.

Eleven of the Biotech Daily Top 40 stocks were up, 16 fell, 11 traded unchanged and two were untraded. All three Big Caps were up.

Atcor was the best, up two cents or 13.8 percent to 16.5 cents with 3.4 million shares traded.

IDT and Psivida climbed more than eight percent; Antisense and GI Dynamics rose more than six percent; Ellex was up 3.45 percent; Acrux, Benitec and Phosphagenics rose more than two percent; Osprey and Universal Biosensors were up more than one percent; with Cochlear, CSL and Resmed up by less than one percent.

Compumedics led the falls, down 1.1 cents or 12.9 percent to 7.4 cents with 262,900 shares traded, followed by Phylogica down 11.1 percent to 1.6 cents with 484,671 shares traded.

Prana lost 8.3 percent; Nanosonics and Patrys fell five percent or more; Starpharma and Tissue Therapies lost four percent or more; Circadian was down 3.7 percent; Bionomics and Prima shed more than two percent; Genetic Technologies and Viralytics were down more than one percent; with Clinuvel, Medical Developments, Mesoblast and Sirtex down by less than one percent.

SUNSHINE HEART

Sunshine Heart says the first patient of up to 388 patients has been implanted in its 'Counter HF' US pivotal trial of its C-Pulse aorta cuff system for heart failure.

Sunshine Heart said that the study was a prospective, randomized, multi-center, controlled trial that would evaluate the safety and efficacy of the C-Pulse system for the treatment of the New York Heart Association Class III and ambulatory Class IV heart failure.

The company said the study would assess the C-Pulse balloon counter-pulsation treatment designed to improve heart function and reduce re-hospitalizations due to worsening heart failure.

Sunshine Heart said the principal study investigator was Kansas City's Saint Luke's Mid America Heart Institute cardiothoracic surgeon Dr Sanjeev Aggarwal.

"The C-Pulse system, in comparison to other devices used for circulatory support, offers the advantage of implantation through a truly minimally invasive approach without the need for cardiopulmonary bypass or sternal division," Dr Aggarwal said.

"Its non-blood contacting interface obviates the need for anticoagulation and allows patients to untether from the device for short periods of time," Dr Aggarwal said.

Sunshine Heart chief executive officer David Rosa said that Saint Luke's Mid-America Heart Institute was "the top enrolling clinical site in our recently completed ... feasibility study and we look forward to their continued leadership in this trial".

Last night on the Nasdaq, Sunshine Heart fell 1.19 percent to \$US10.78 (\$A11.66, equivalent to 5.8 cents before the company left the ASX) with 592,232 shares traded.

PRANA BIOTECHNOLOGY

Prana says its trial of PBT2 for Huntington's disease has been completed but the results will be delayed several months.

Prana said that the trial successfully completed at the end of July 2013 with 95 percent of participants completing the six months of treatment.

The company said there was "a delay in finalizing the database to achieve 'database lock', required before statistical analysis of the data may begin".

Prana said the results were expected by the end of 2013 and were now expected "to be reported early in 2014".

Prana executive chairman Geoffrey Kempler said that "apart from the timing delay, which is disappointing, nothing has changed".

"The trial was conducted and completed to protocol and will provide the robust data needed to meet with the FDA in 2014," Mr Kempler, said.

Prana said that its 12-month, double-blind, placebo-controlled phase II trial in 42 prodromal and mild Alzheimer's disease patients imaging trial enrolled the last patient on November 28, 2012 and 17 patients had completed the 12 months of treatment.

The company said that the data safety monitoring board met four times and recommended the trial continue without changes to the protocol.

Prana said the last patient would finish dosing at the end of November 2013 with results expected by April 2014.

The company said that the imaging extension open label trial was approved allowing all patients who completed the trial to participate for a further 12 months.

Prana said that enrolment opened on July 23, 2013 and eight of 12 patients who had completed treatment joined the extension trial, with a further five patients completing treatment and joining the extension trial to receive PBT2 for an additional 12 months.

Prana fell 4.5 cents or 8.3 percent to 49.5 cents with 1.95 million shares traded.

ONCOSIL MEDICAL

Oncosil says it has raised \$7.8 million through a “heavily oversubscribed” placement at 13 cents a share and hopes to raise a further \$2.5 million through a share plan.

Oncosil said the proceeds would fund a global registration study of up to 300 patients for its Oncosil localized radiation therapy for pancreatic cancer, due to begin in 2014.

The company said the record date for the plan, would be September 16, 2013 and shares would be available and scaled back on a first-come, first-served basis.

Oncosil said that director and Neurodiscovery founder David McAuliffe and company secretary Robert Hodby had resigned from the company effective today.

Oncosil was up one cent or 6.9 percent to 15.5 cents with 2.5 million shares traded.

ACTINOGEN

Actinogen says it has begun preparations to close its laboratory space at the Queen Elizabeth II Medical Centre in Nedlands, Western Australia.

Actinogene said the decision was “part of the cost saving exercise and the decision to recapitalize the company”.

Actinogen has been developing the use of actinomycetes for antibiotics and anti-fungals and more recently bio-fuels (BD: Nov 9, 2011).

In October 2012 the company had less than three months of cash and in August 2013 failed to raise \$595,000 in a rights issue (BD: Oct 29, 2012; Aug 2, 2013).

Earlier this week Actinogen said that it would be recapitalized by Otsana capital for an agricultural project, pending shareholder approval.

Actinogen said it employed one full-time scientist and one part-time scientist but it could not renew the employment contracts due to a lack of working capital.

Actinogen fell 0.2 cents or 20 percent to 0.8 cents.

COCHLEAR

Cochlear's annual general meeting will vote on a potential second strike board spill, along with the issue of options to chief executive officer Dr Chris Roberts worth \$1,400,000.

In 2012, Cochlear's remuneration report vote was opposed by 10,355,483 votes or 31.0 percent and supported by 24,112,162 votes (69%), providing the first trigger for a potential board spill at this year's meeting (BD: Oct 16, 2012).

Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 a company with a vote of 25 percent or more against the remuneration report in two successive annual meetings must vote on a board spill and if passed by a majority, directors must stand for reelection at a subsequent meeting.

The company's notice of meeting said that the company proposed to issue Dr Roberts 123,032 options, conditional on meeting earnings per share and total share value hurdles, at a value of \$11.38 each equaling 100 percent of his fixed remuneration and exercisable at \$59.13 within 3.4 years.

Cochlear chief financial officer Neville Mitchell told Biotech Daily that the options would vest on July 1, 2016 and expire in March 2017, giving Dr Roberts several ‘trading windows’ to exercise the options.

Cochlear said that other resolutions included the re-election of directors Donal O'Dwyer and Yasmin Allen and the remuneration report.

The meeting will be held at the Australian Securities Exchange, Exchange Square Auditorium, 20 Bridge Street, Sydney on October 15, 2013 at 10am (AEDT).

Cochlear was up seven cents or 0.1 percent to \$60.00 with 438,582 shares traded.

CSL

CSL will vote on 25,000 'performance rights to chief executive officer Paul Perreault and \$5 million in 'termination benefits' to former chief executive officer Dr Brian McNamee. CSL said that Mr Perreault's performance rights were granted for neo fee and exercisable as shares at no cost.

The company said the rights were 60 percent of Mr Perreault's base salary of \$US1.7 million and had a target value of \$US1.02 million (\$1,104,160).

CSL said that as at Dr McNamee's cessation of employment on October 15, 2013, he would be entitled to a cash payment for any accrued but unpaid fixed remuneration in respect of his employment and a cash payment in lieu of accrued but untaken annual leave and long service leave entitlements.

The company said the amounts were estimated to be \$1,136,670 or 102.50 days for annual leave, and \$959,738 or 86.55 days for long service leave.

CSL said that Dr McNamee was entitled to cash payments in future related to the outstanding deferred cash component of his short term incentive or bonus earned in respect of the financial years ended 30 June in each of 2011, 2012 and 2013.

The company said that a severance payment equal to the average annual fixed remuneration received by Dr McNamee during the last three years which was expected to be \$2,819,880 and any benefits which Dr McNamee received from his retention of outstanding vested or unvested rights and options under the performance rights plan.

The company's notice of meeting said it would also seek shareholder approval for the re-election of directors John Akehurst and Marie McDonald.

The meeting will be held at the Function Centre, National Tennis Centre, Melbourne Park, Batman Avenue, Melbourne on October 16, 2013 at 10am (AEDT).

CSL was up 62 cents or 0.95 percent to \$65.90 with 1.6 million shares traded.

BENITEC BIOPHARMA

Benitec says it has won the University of New South Wales People's Choice Innovation Award for its lung cancer program with the Children's Cancer Institute Australia.

Benitec said the collaboration was developing a treatment for chemotherapy resistant lung cancer, using its DNA-directed RNA interference (ddRNAi) gene silencing technology.

The company said that Children's Cancer Institute head of tumor biology and targeting program and University of New South Wales Faculty of Medicine Prof Maria Kavallaris accepted the award and said it was "clear recognition of the importance of our program for millions around the world".

"We are working on finding a better way to treat the most common cancer worldwide, lung cancer, whose prognosis remains dire," Prof Kavallaris said.

"With Benitec Biopharma we are developing a gene silencing treatment to overcome the resistance of the cancer to chemotherapy drugs and our initial data has exceeded our most optimistic expectations," Prof Kavallaris said.

Benitec chief executive officer Dr Peter French said the company was "committed to taking this program into clinical trials" in late 2014.

Benitec was up one cent or 2.7 percent to 38 cents.