



# Biotech Daily

Thursday February 7, 2013

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH UP: SUNSHINE HEART UP 30%, CLINUVEL DOWN 10%**
- \* **GREENS, LIBS MOVE FOR SCIENCE, RESEARCH BUDGET PROTECTION**
- \* **US, CHINA PATENTS FOR MESOBLAST COMPOSITION-OF-MATTER**
- \* **REVA 6-MONTH FOLLOW-UP: 'NO FURTHER MAJOR EVENTS'**
- \* **NEURODISCOVERY \$1.5m, DR ASTON CHAIR, PHASE III BRACHYSIL**
- \* **BIONICHE HUNTS FOR NEW PARTNERS FOR UROCIDIN**
- \* **PRIMA EARNS \$1.4m FEDERAL R&D TAX REFUND**
- \* **CIRCADIAN \$1.3m FEDERAL R&D TAX REFUND**
- \* **SUNSHINE HEART CEO DAVID ROSA \$322k BASE SALARY**
- \* **INSURER JOINS INVION (CBIO) ACTION AGAINST FORMER EXECUTIVES**

## MARKET REPORT

The Australian stock market was up 0.3 percent on Thursday February 7, 2013 with the S&P ASX 200 up 14.7 points to 4,935.7 points. Seventeen of the Biotech Daily Top 40 stocks were up, 11 fell, seven traded unchanged and five were untraded.

Sunshine Heart was the best, up 0.9 cents or 30 percent to 3.9 cents with 4.4 million shares traded, followed by Mesoblast was up 11.6 percent to \$7.49 with 961,690 shares traded.

Reva climbed 9.9 percent; Neuren was up 8.1 percent; Phylogica was up 7.7 percent; Impedimed rose 6.1 percent; Tissue Therapies was up 5.8 percent; Alchemia, Avita and Universal Biosensors were up more than four percent; Anteo, Bionomics and QRX were up more than three percent; Psivida and Starpharma rose more than two percent; with CSL, Heartware, Nanosonics and Resmed up by less than one percent.

Clinuvel led the falls, down 25 cents or 10.2 percent to \$2.20 with 4,289 shares traded.

Antisense lost 7.1 percent; Allied Health and Phosphagenics were down more than three percent; Pharmaxis, Prana and Sirtex shed more than two percent; Acrux, Cochlear, Genetic Technologies and Viralytics were down more than one percent; with Medical Developments down half a percent.

## FEDERAL PARLIAMENT

The Federal Member for Melbourne Adam Bandt narrowly lost a suspension of standing orders motion to move to protect the science and research budget.

The suspension of standing orders vote was passed by 74 votes in favor and 66 votes against.

The Office of the Speaker of the House of Representatives told Biotech Daily that an absolute majority of 76 votes of the 150 members is required to pass a suspension of standing orders motion.

The motion to protect the science and research budget is expected to be heard next week. In proposing the suspension of standing orders, Deputy Leader of the Greens, Mr Bandt called on the Government to protect the science and research budget from cuts to enable the creation of a Budget surplus.

“Science and Research should not be a honeypot for Government to go back to every time it needs money to balance its Budget,” Mr Bandt said.

Mr Bandt named a range of programs including the National Health and Medical Research Council budget that should be protected from cuts in this year’s Budget.

Mr Bandt told the Parliament that the suspension of standing orders motion was moved because a motion to protect the science and research budget which had been listed to be heard today was removed, possibly because the Government thought it might succeed with the support of the Coalition and independents.

The motion was seconded by the Liberal Member for Higgins Kelly O’Dwyer, whose inner south-east Melbourne electorate includes the Cabrini Hospital as well as several biotechnology companies and the office of industry organization Ausbiotech.

Ms O’Dwyer is a co-founder of the Parliamentary Friends of Women in Science, Mathematics and Engineering group.

“Health and medical research is critical to Australia’s future and should be a strategic priority,” Ms O’Dwyer said in a media release.” With a hub of world class universities and research institutes based in Melbourne, it is particularly critical for Victoria.”

## MESOBLAST

Mesoblast says it has been granted three key patents by the US Patent and Trade Mark Office and China’s State Intellectual Property Office.

Mesoblast said that US patent number 8,367,405, entitled ‘Isolation of adult multipotential cells by tissue non-specific alkaline phosphatase’ gave exclusive rights to March 2029 to compositions-of-matter covering its products and extended by more than seven years the company’s exclusive US commercial rights.

The company said that two Chinese patents entitled ‘Multipotential Expanded Mesenchymal Precursor Cell Progeny (MEMP) and Uses Thereof’ and ‘Method of enhancing proliferation and/or survival of Mesenchymal Precursor Cells’ provided exclusive mesenchymal precursor cell product commercial rights and protection to 2025.

Mesoblast said that the provided long-term composition-of-matter protection for the company’s mesenchymal precursor cell products derived from an unlimited range of tissue sources, such as bone marrow, adipose tissue, placenta, umbilical cord, and dental pulp. The company said that the Chinese patents underpinned Mesoblast’s corporate strategy to target the world’s largest emerging market for regenerative medicines and to protect its manufacturing processes and know-how.

Mesoblast said the patents “deliver major commercial advantages and offer long term protection in these territories for the company’s products based on its proprietary mesenchymal precursor cell adult stem cell technology platform”.

Mesoblast was up 78 cents or 11.6 percent to \$7.49 with 961,690 shares traded.

## REVA MEDICAL

Reva says all 22 patients in its Rezolve bioresorbable cardiac stent pilot trial have completed six-month follow-up, with no additional reported clinical events.

Reva chairman and chief executive officer Robert Stockman wrote in a letter to shareholders that the company completed enrollment in 2012 and reported interim data, including data on a subset of 12 patients that had completed six-month clinical follow-up, at the Transcatheter Therapeutics Conference (BD: Oct 24 2012).

Reva said at that time that there had been two major adverse coronary events.

Today, Mr Stockman said that there were no reported blood clots or thrombosis in those patients, no reported incidences of myocardial infarction or heart attack and a low rate of major adverse coronary events.

"Today, all 22 patients have completed six-month follow-up and we are pleased to announce that there have been no additional reported clinical events through the six-month time point," Mr Stockman said.

"During 2013 these patients will undergo a 12-month imaging assessment to quantitatively evaluate scaffold performance," Mr Stockman said.

"This will be accomplished by looking inside the stented artery to evaluate the amount of residual obstruction as well as overall healing," Mr Stockman said.

"We completed imaging assessments in two patients at an early six-month time point, and our first patient has now undergone a 12-month imaging assessment," Mr Stockman said.

"In these three cases the stented artery is wide open ... and it is evident the device is performing as designed," Mr Stockman said.

Mr Stockman said the company would present more comprehensive clinical and imaging data, including any change in major adverse coronary events between six and 12 months, at the Paris Course on Revascularization in France in May 2013.

Reva was up 4.5 cents or 9.9 percent to 50 cents.

## NEURODISCOVERY

Neurodiscovery has raised \$1.5 million, appointed Dr Roger Aston chairman-elect and agreed to acquire the UK-based Enigma Therapeutics for Psivida's Brachysil.

Neurodiscovery said that Engima's lead product, Oncosil was a targeted brachy-therapy treatment developed under a licence from Psivida's Psimedica for its Brachysil product.

Neurodiscovery said that Oncosil had completed two phase II studies as Brachysil in pancreatic cancer and a phase III study was planned to begin in 2013.

The company said it would apply for Conformité Européenne (CE) mark approval as soon as possible following discussions with relevant regulatory authorities.

Neurodiscovery said that, subject to shareholder approval, it would issue 75 million shares to buy 100 percent of Enigma and had raised an additional \$1.5 million through the placement of 60 million shares at 2.5 cents a share.

The company said it would issue 25 million unlisted options to placement manager Forrest Capital exercisable at five cents an option by June 30, 2016, with one million options to each director on the same terms.

Neurodiscovery said Brachysil had completed four phase II studies in liver and pancreatic cancer and was phase III ready, subject to regulatory approval (BD: Oct 22, 2009).

The company said that Dr Aston was a founding director of Psivida and inventor of Brachysil, a radioactive particle of silicon and phosphorus inserted directly into a tumor and studies showed a significant increase in survival (121 days to 309 days), tumor size reduction and pain reduction.

Neurodiscovery was up 0.9 cents or 31 percent to 3.8 cents with 7.4 million shares traded.

### BIONICHE LIFE SCIENCES

Bioniche president and chief executive officer Grame McRae says he is in negotiations to find a partner for the company's phase III Urocidin for bladder cancer.

Bioniche has previously said it had conducted a phase III trial of Urocidin which was being repeated by partner Endo Pharmaceuticals, until Endo closed its phase III trial and handed the drug back to Bioniche last year (BD: Nov 6, 2012).

"The return of global rights to our phase III human health bladder cancer product, Urocidin, from Endo in December was a significant event in the life of the company," Mr McRae said.

"We are already in discussions with new potential partners for the technology and are actively strategizing around a new clinical plan to advance the product to registration, bearing in mind that we will be unable to meet with regulatory authorities until after the end of March, when clinical sponsorship is returned to us from Endo," Mr McRae said.

Bioniche was unchanged at 25 cents.

### PRIMA BIOMED

Prima says it has received \$1,442,120 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Prima said the funds related to research and development expenditure for the year to June 30, 2012.

Prima was unchanged at 11 cents with 1.8 million shares traded.

### CIRCADIAN TECHNOLOGIES

Circadian says it has received \$1,353,136 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Circadian said the funds related to research and development expenditure for the year to June 30, 2012.

Circadian was untraded at 31.5 cents.

### SUNSHINE HEART

Sunshine Heart says chief executive officer Dave Rosa will have an annual base salary of at least \$US332,072 (\$A321,946).

Sunshine Heart said that the executive employment agreement included the issue of a stock option for 347,000 shares of common stock (69,400,000 CDIs) with an exercise price of \$US6.46 per share (3.23 cents per CDI) "which the company agreed to issue upon the earlier of (i) the date on which the listing rules of the Australian Stock Exchange no longer apply to the grant or (ii) stockholder approval of the issuance of such stock option at the next meeting of the company's stockholders in accordance with the listing rules of the Australian Securities Exchange"

The company has applied to delist from the ASX, which is expected to occur on May 6, 2013 (BD: Feb 5, 2013).

Sunshine Heart said that Mr Rosa should have the opportunity to receive an annual performance bonus of up to 30 percent of the annual base salary, based on achievement of performance goals; participation in welfare benefits, reimbursement of reasonable expenses and four weeks paid leave.

Sunshine Heart was up 0.9 cents or 30 percent to 3.9 cents with 4.4 million shares traded.

## INVION

Invion (formerly CBio) says legal action is continuing to recover about \$1.2 million from four former executives including former chairman Steve Jones.

Last year, Invion said the former executives were being sued for \$1,200,000 and had lodged a counterclaim for \$1,246,666.96 (BD: Oct 23, 2012).

Invion said that it began proceedings against Mr Jones, the chief executive officer, chief financial officer and company secretary in February 2012 relating to their resignations on or about October 12, 2011 and gross payments made to the officers (BD: Jun 25, 2012)

Today Invion said that the Supreme Court of Queensland yesterday heard an application by the defendants to join additional parties to the proceedings, McCullough Robertson Lawyers and Invion's directors and officers insurer, Chartis Australia Insurance.

Invion said the Court dismissed the application to join McCullough Robertson Lawyers and the defendants were ordered to pay Invion's costs of and incidental to the application to join McCullough Robertson Lawyers.

The company said that Chartis consented to be joined to the proceedings, and the Court so ordered.

Invion said that it did not expect that the joining of Chartis would cause a significant delay in the conduct of the proceedings.

Invion was untraded at 6.4 cents.