



Biotech Daily

Monday October 21, 2013

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: PHYLOGICA UP 17%, PSIVIDA DOWN 27%**
- * **FDA REJECTS PSIVIDA'S ILUVIEN FOR DME, AGAIN - NEW TRIAL**
- * **FDA APPROVES IROKO, ICEUTICA PERTH-INVENTED NANO-DICLOFENAC**
- * **NOVOGEN DRAWS DOWN FURTHER HUDSON BAY \$1m**
- * **ANTEO TO TRIAL MIX&GO MAGNETIC BEADS, PLATES**
- * **PHARMAXIS AGM FOR 2m CEO 'PERFORMANCE RIGHTS'**
- * **ALLIED HEALTH AGM FOR 7m DIRECTOR OPTIONS, NAME CHANGE**
- * **CELLMID AGM FOR 12m CEO LOAN SHARES**
- * **IDT CHAIRMAN DR GRAEME BLACKMAN INCREASES, DILUTED TO 9%**
- * **HUNTER HALL DOWN TO 18% OF SIRTIX**
- * **IMUGENE REQUESTS ACQUISITION, CAPITAL RAISING TRADING HALT**

MARKET REPORT

The Australian stock market was up 0.57 percent on Monday October 21, 2013 with the S&P ASX 200 up 30.3 points to 5,351.8 points. Sixteen of the Biotech Daily Top 40 stocks were up, 14 fell, eight traded unchanged and two were untraded.

Phylogica was the best, up 0.3 cents or 16.7 percent to 2.1 cents with one million shares traded, followed by Benitec up 15.45 percent to 71 cents, Prima up 13.9 percent to 4.1 cents and Allied Health up 10 percent to 11 cents. Atcor and Reva climbed more than five percent; both Clinuvel and Pharmaxis rose four percent; Cellmid, Impedimed and Optiscan were up more than three percent; Alchemia and Sirtex rose more than two percent; GI Dynamics, IDT and Resmed were up more than one percent; with Acrux and Cochlear up by less than one percent.

Psivida led the falls for the second trading day in a row, down \$1.04 or 27.1 percent to \$2.80 with 96,617 shares traded, followed by Uscom down 11.1 percent to 16 cents. Phosphagenics fell 8.6 percent; Medical Developments and Viralytics lost more than five percent; Genetic Technologies and Living Cell were down more than three percent; Anteo, Mesoblast, Nanosonics, Starpharma, Tissue Therapies and Universal Biosensors were down more than one percent; with CSL and QRX down by less than one percent.

PSIVIDA

Psivida says the US Food and Drug Administration has rejected a third new drug application for Iluvien for diabetic macular oedema and called for a new trial.

The original application received an FDA 'complete response letter' in December 2010 and a second rejection in 2011 (BD: Jan 16, Nov 14, 2011).

The revised third application for the sub-group of patients with chronic diabetic macular oedema (DME) was hoped to resolve the 2011 FDA criticism that "the NDA did not provide sufficient data to support that Iluvien is safe and effective in the treatment of patients with DME".

In 2011, Psivida fell \$2.00 or 48.8 percent to \$2.10 on the FDA rejection which said FDA saying that "the risks of adverse reactions shown for Iluvien ... were significant and were not offset by the benefits demonstrated by Iluvien in these clinical trials" and requested two additional trials.

Psivida has previously said that Iluvien had marketing approval in six European Union countries for chronic diabetic macular oedema, was commercially available in the UK and Germany and has been recommended for reimbursement in France and UK for patients who have had cataracts surgery (BD: Mar 25, May 8, Jul 25, 2013).

Today Psivida said the FDA had "concerns regarding the benefit to risk and safety profiles of Iluvien ... [and] the NDA could not be approved in its present form".

The FDA recommended a new clinical trial with at least 12 months follow-up.

Psivida's head of investor relations Brian Leedman told Biotech Daily that Alimera would meet with the FDA on January 27, 2014 to discuss a way forward for Iluvien.

Psivida said the FDA suggested that a meeting with the Dermatologic and Ophthalmic Drugs Advisory Committee might be of assistance in addressing the deficiencies identified and providing advice whether a patient population could be identified in which the benefits of the drug product might outweigh the risks.

The company said that the FDA complete response letter also referenced deficiencies at the facility where Iluvien was manufactured.

Psivida chief executive officer Dr Paul Ashton said the company was "extremely disappointed by the FDA's decision not to approve Iluvien at this time".

"However, we are pleased that Alimera plans to continue to work with the FDA ... to determine whether there is a path forward in the US for Iluvien and that Alimera believes it is well positioned for growth in Europe, irrespective of the US outcome, based on current traction in the countries in which Iluvien has already been approved, coupled with the continued pursuit of further country approvals," Dr Ashton said.

Psivida said that Alimera has filed with the UK Medicines and Healthcare Products Regulatory Agency as the reference member state for 10 additional European Union country approvals through the mutual recognition procedure.

Psivida fell \$1.04 or 27.1 percent to \$2.80.

IROKO PHARMACEUTICALS

The Philadelphia, Pennsylvania-based Iroko Pharmaceuticals says the US Food and Drug Administration has approved its Zorvolex (diclofenac) capsules.

Iroko said the nonsteroidal anti-inflammatory drug for mild to moderate acute pain in adults was approved at dosage strengths 20 percent lower than currently available diclofenac products.

In 2011, based Iroko acquired the Perth-founded Iceutica for its nanotechnology drug delivery platform technology (BD: Apr 27, 2011).

Iceutica was partly funded by the Western Australia-based Yuuwa Capital.

NOVOGEN

Novogen says it has issued a second convertible security to Hudson Bay Capital raising a further \$1 million for its drug development program (BD: Jul 4, 2013).

Novogen chief executive officer Dr Graham Kelly said the company recently announced the acquisition of the anti-tropomyosins drug development platform (BD: Oct 9, 2013).

"The funds raised through the issuance of this convertible security will be applied to the development of that drug platform," Dr Kelly said.

Novogen fell half a cent or 2.6 percent to 19 cents.

ANTEO DIAGNOSTICS

Anteo says it will release two new Mix&Go products for beta-testing during the Ausbiotech national conference in Brisbane on October 30, 2013.

Anteo said the two products from its Mix&Go glue for binding fragile molecules were targeted at academic and industry researchers and provided an easy-to-use, high-performance alternative to existing products.

The company said that Mix&Go Magnetic Beads were coated with Mix&Go and functionalized with streptavidin, a molecule frequently used in research for the specific capture and purification of desired proteins.

Anteo said its Mix&Go Plates were coated with Mix&Go and functionalized with streptavidin for use in research to detect and quantify the presence of a desired protein.

The company said that the beta-test trial would allow it to work closely with researchers, obtain their feedback on possible improvements in product presentation and documentation and encourage use in novel areas.

Anteo chief executive officer Dr Geoff Cumming said that researchers were typically early adopters of new technologies and demonstrating the utility of Mix&Go would broaden awareness of the possible practical applications that would benefit from Mix&Go use.

"Getting feedback from researchers is invaluable to us," Dr Cumming said.

"It's a great way of learning about new applications for our products that we may not have thought of," Dr Cumming said. "In addition, taking these two promising products from concept through the whole development cycle and now through beta testing, has allowed us to build and develop skills in [quality control] and manufacturing that the company will benefit from greatly in the future."

Anteo said it planned the commercial release of the products by April 2014.

Anteo fell 0.1 cents or 1.7 percent to 5.8 cents.

PHARMAXIS

Pharmaxis will vote to issue chief executive officer Gary Phillips 2,000,000 performance rights, at no cost and exercisable for shares at no charge.

Pharmaxis said the performance rights would be valid for 10 years and vest in three instalments with 30 percent vesting on January 31, 2014 with no performance criteria designed to provide a retention incentive in "a particularly challenging time"; with 35 percent vesting on each of July 31, 2014 and July 31, 2015 subject to corporate and personal objectives.

The company's notice of meeting said it would also seek shareholder approval for the remuneration report and the re-election of chairman Malcolm McComas.

The meeting will be held at the Christie Conference Centre, 3 Spring Street, Sydney, on November 27, 2013 at 2.30pm (AEST).

Pharmaxis was up half a cent or four percent to 13 cents with 2.5 million shares traded.

ALLIED HEALTHCARE GROUP

Allied Health will vote to change its name to Admedus, grant three directors shares in lieu of pay and issue 7,000,000 options to directors.

Allied said that as it expanded into international jurisdictions it was unable to consistently use the current name.

The company said the name Admedus would provide "a unique and recognizable brand and clearly distinguish [it] and its products in international markets".

Allied said that it proposed to issue chairman Christopher Catlow \$45,000 in shares, and directors Graeme Rowley and Peter Turvey \$35,000 each in shares, valued at the five-day volume weighted average price at the date of issue.

The company said it proposed to issue managing director Lee Rodne 3,000,000 options vesting in three tranches over three years and exercisable at 167 percent of the five-day volume weighted average price at the date of issue within five years of issue.

Allied said that it proposed to issue director Michael Bennett 1,300,000 options, Mr Catlow 900,000 options, Mr Rowley 500,000 options and Mr Turvey 500,000 options, all on the same terms as Mr Rodne's options.

The company's notice of meeting said it would also seek shareholder approval for the remuneration report, the ratification of a prior placement and the re-election of directors Mr Catlow and Mr Rowley.

The meeting will be held at the Duxton Hotel, 1 St George Terrace, Perth, Western Australia on November 20, 2013 at 12pm (AWST).

Allied was up one cent or 10 percent to 11 cents with 7.4 million shares traded.

CELLMID

Cellmid will vote to issue chief executive officer Maria Halasz 12,000,000 loan shares worth \$360,000 in three tranches over three years, pending clinical and revenue hurdles. Cellmid said the shares were valued at the five-day volume weighted average price to October 15, 2013 at three cents a share and the interest-free loan had a term of five years.

The company said that one-third of the loan shares would be issued on revenue exceeding \$4 million over a 12-month period; a further third for the first patient enrolled in a midkine antibody clinical trial; and the final third pending a diagnostic or therapeutic licence or a distribution deal for its hair loss products outside Japan and Australia.

Cellmid said other resolutions included the issue of 3,515,625 shares and options for the Advangen acquisition and a prior placement.

The company's notice of meeting said it would also seek shareholder approval for the remuneration report and the re-election of chairman Dr David King.

The meeting will be held at the Cliftons, Level 13, 60 Margaret Street, Sydney, on November 22, 2013 at 11am (AEDT).

Cellmid was up 0.1 cents or three percent to 3.4 cents with 1.9 million shares traded.

IDT AUSTRALIA

IDT executive chairman Dr Graeme Blackman has increased his holding from 5,830,313 shares to 6,996,376 shares but has been diluted from 13.56 percent to 9.26 percent.

The company raised \$2 million in a rights issue in September and a further \$3.1 million in a placement last week, both at 27 cents a share (BD: Sep 27, Oct 17, 2013).

IDT was up half a cent or 1.35 percent to 37.5 cents.

SIRTEX MEDICAL

Hunter Hall Investment Management has again reduced its substantial holding in Sirtex, this time from 10,506,023 shares (18.73%) to 9,938,637 shares (17.71%).

The Sydney-based Hunter Hall said it sold 567,386 shares between July 11 and October 17, 2013 with the single largest sale 200,000 shares for \$2,544,862 or \$12.72 a share.

In May, Hunter Hall reduced its holding in Sirtex from 23.77 percent to 22.26 percent and in June and July further reduced to 18.73 percent (BD: May 29, Jun 28, Jul 12, 2013).

Hunter Hall has been a long term shareholder in Sirtex and in 2009 increased to 16,684,884 shares (29.92%) when the company was at \$2.35 a share (BD: Mar 5, 2009). Sirtex was up 31 cents or 2.5 percent to \$12.69 with 142,093 shares traded.

IMUGENE

Imugene has requested a trading halt pending the release of an announcement "in relation to a proposed acquisition and capital raising".

Trading will resume on October 23, 2013 or on an earlier announcement.

Imugene last traded at 1.2 cents.