



# Biotech Daily

Thursday May 22, 2014

*Daily news on ASX-listed biotechnology companies*

- \* **ASX UP, BIOTECH DOWN: UNIVERSAL BIO UP 17%, BENITEC DOWN 8%**
- \* **FDA ORPHAN STATUS FOR CLINUVEL'S SCENESSE FOR HAILEY-HAILEY**
- \* **UP TO 10% OF GI DYNAMICS OPPOSE CEO STUART RANDLE STOCK**
- \* **MINDEROO (METAL) GROUP REDUCES, DILUTED TO 13% OF ADMEDUS**

## MARKET REPORT

The Australian stock market was up 1.02 percent on Thursday May 22, 2014 with the S&P ASX 200 up 55.3 points to 5,479.9 points.

Twelve of the Biotech Daily Top 40 stocks were up, 14 fell, 11 traded unchanged and three were untraded. All three Big Caps were up.

Universal Biosensors was the best, up 2.5 cents or 17.2 percent to 17 cents with 2.2 million shares traded.

Anteo climbed 9.8 percent; Uscom was up eight percent; Ellex and Prana were up more than six percent; Neuren was up 5.6 percent; Pharmaxis was up 4.5 percent; Sirtex climbed 3.6 percent; Bionomics, Cochlear and Starpharma rose more than two percent; with CSL, Mesoblast, Phosphagenics and Resmed up by more than one percent.

Benitec led the falls, down 10.5 cents or 8.3 percent to \$1.165 with 677,902 shares traded.

Both Avita and IDT fell 4.35 percent; both Antisense and Viralytics lost 3.45 percent; Analytica, Impedimed, Patrys and Tissue Therapies shed more than two percent; Nanosonics was down 1.9 percent; with Alchemia, Clinuvel, GI Dynamics and Osprey down by less than one percent.

## CLINUVEL PHARMACEUTICALS

Clinuvel says the US Food and Drug Administration has granted orphan-drug designation to afamelanotide, the active ingredient in Scenesse, for Hailey-Hailey disease.

On Monday, the European Medicines Agency granted Scenesse orphan designation for Hailey-Hailey disease or familial benign chronic pemphigus (BD: May 19, 2104).

The company said that FDA orphan designation was granted to drugs which had the potential to diagnose or treat rare conditions, affecting fewer than 200,000 individuals in the US and entitled recipients to technical assistance in the development process, potential fee reductions and tax credits and seven years market exclusivity, if approved.

Clinuvel acting chief scientific officer Dr Dennis Wright said the designation was the second from a major regulatory agency “to recognize the potential of afamelanotide” to treat Hailey-Hailey disease patients, who currently lacked an effective therapy.

Clinuvel said that Scenesse was being evaluated as a therapy for Hailey-Hailey disease in a phase II study in Italy.

Clinuvel fell half a cent or 0.3 percent to \$1.455.

## GI DYNAMICS

The GI Dynamics annual general meeting voted strong dissent against the grant of 38,280 stock units and 133,982 stock options to chief executive officer Stuart Randle.

The resolution to provide the shares and options equivalent to 191,400 Chess depository interests (CDIs) and 669,910 CDI options was opposed by 9,549,704 votes (25.5%), with 27,936,476 votes (74.5%) in favor.

The company’s most recent Appendix 3B new issue announcement said that GI Dynamics had the equivalent to 473,570,270 CDIs on issue or the equivalent to 94,714,054 common shares or votes, meaning that the votes against Mr Randle’s stock issue amounted to 10.1 percent of the company, sufficient to requisition extraordinary general meetings under the Australian Corporations Act.

GI Dynamics is a Delaware US-incorporated company and according to the company’s constitution ‘special meetings’ can only be called by either a majority of the whole of board resolution or by “stockholders holding at least a majority of the voting power of all the then outstanding shares ... entitled to vote at an election of directors”, that is more than 50 percent of the shareholding.

Resolutions to re-elect Mr Randle and director Jack Meyer were passed unopposed, with the change of accountant resolution passed by 40.3 million votes to 2,000 votes.

GI Dynamics fell half a cent or 0.9 percent to 53 cents.

## ADMEDUS

Minderoo Group says it has reduced and its substantial holding in Admedus has been diluted from 181,383,241 shares (14.44%) to 173,027,958 shares (12.91%).

Minderoo, formerly the Metal Group, associated with Western Australian miner Andrew Forrest, said it sold the 8,355,283 shares for \$1,070,069 or 12.8 cents a share.

Admedus was unchanged at 11 cents with 5.7 million shares traded.