



Biotech Daily

Tuesday March 27, 2012

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: USCOM UP 12%, CELLMID DOWN 8%**
- * **TISSUE THERAPIES VITROGRO CE MARK DELAY 'COMMERCIAL BENEFIT'**
- * **WEHI RESEARCHERS SHARE \$US2.4m GRANTS**
- * **MEDTRONIC HOLDS 8% OF REVA; REVA FILES SUBSTANTIAL NOTICES**
- * **M&G GROUP HOLDS 11% OF GI DYNAMICS**

MARKET REPORT

The Australian stock market was up 0.9 percent on Tuesday March 27, 2012, with the S&P ASX 200 up 38.5 points to 4,301.3 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 15 fell, eight traded unchanged and four were untraded. All three Big Caps were up.

Uscom was best on small volumes, up one cent or 11.8 percent to 9.5 cents, with 4,000 shares traded, followed by Pharmaxis up 7.8 percent to \$1.375 with 1.4 million shares traded and Phosphagenics up 6.5 percent to 24.5 cents with 7.2 million shares traded.

Genera climbed 5.9 percent; Avita, Living Cell and Tissue Therapies were up more than four percent; Cochlear was up 3.8 percent; Bionomics and Mesoblast rose more than two percent; Alchemia, CSL, Psivida and Resmed were up more than one percent; with Acrux and Starpharma up by less than one percent.

Cellmid led the falls, down 0.1 cents or 8.3 percent to 1.1 cents with 650,000 shares traded.

Antisense and Benitec fell five percent or more; Allied Health, Impedimed and QRX lost more than three percent; Genetic Technologies, Patrys, Phylogica and Prima shed more than two percent; Anteo, Biota, Nanosonics and Reva were down more than one percent; with Clinuvel down half a percent.

TISSUE THERAPIES

Tissue Therapies says it has delayed its final submission for Conformité Européenne (CE) mark approval for its Vitrogro wound treatment for commercial reasons.

Tissue Therapies chief executive Dr Steven Mercer said the company expected CE mark approval by the end of May 2012, "well before the planned start of sales during the last week of June 2012".

"Our recruitment of experienced European sales personnel has been carefully timed to coincide with the start of the new European calendar business year," Dr Mercer said.

Dr Mercer told Biotech Daily that sales staff hiring was "proceeding well but there were limits on when some key staff could become available, determining the start of sales in June 2012".

"There is strong interest already in Vitrogro from key wound care clinical staff in the UK and Europe and the sales and marketing campaign is ready to proceed immediately following CE Mark approval," Dr Mercer said.

Tissue Therapies said the sales and marketing launch plan included conference presentations, publications, advertising, marketing materials and a major website revision, including multilingual capabilities.

Dr Mercer said that historic changes in the wound treatment market were magnifying the competitive advantages of Vitrogro and his company.

"Insurers, reimbursement agencies and governments are increasingly demanding solid science, strong clinical results and convincing health economic data," Dr Mercer said.

"This data has not traditionally been required for the approval and reimbursement of wound care products and Tissue Therapies is one of very few wound care companies that can supply all of this," Dr Mercer said.

The company said the final submission could have been made earlier, but there were commercially important benefits in minimizing the time between approval and the start of sales, such as deferral of the final submission by two months would extend the expiry date of the initial batches of Vitrogro by two months.

Tissue Therapies said that repackaging Vitrogro for expiry date extension would be uneconomic and any unsold stock of Vitrogro finished product with the initial expiry date might have to be destroyed when expiry was reached in September 2013.

The company said that the extension of the expiry date of the initial batches of Vitrogro by two months deferred the costs of manufacturing the next batch by two months.

Tissue Therapies said that deferral of the final CE data submission by two months also delivered the additional benefit of allowing time for completion of the validation data required for US Food and Drug Administration submissions, saving future time and costs for FDA approvals.

Tissue Therapies said that Vitrogro extracellular matrix (ECM) was a biomimetic scaffold that was sterile, acellular and flowable or designed to be applied to the surface of wounds.

The company said the Vitrogro was an artificially created matrix protein designed from polypeptide sequences that normally provide attachment sites in healthy skin that guide cells during normal wound healing

Tissue Therapies said that in chronic or non-healing wounds, skin cells were deprived of these attachment sites because the extracellular matrix was degraded.

Tissue Therapies was up two cents or 4.9 percent to 43 cents with 1,048,659 shares traded.

THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says that malaria researcher Dr Justin Boddey and immunologist Prof Phil Hodgkin have won Human Frontier Science Program grants. WEHI said that Dr Boddey had won a \$US1.05 million young investigator grant to study the early stages of malaria infection, in the hope of finding new ways to treat the disease. The Institute said Dr Boddey studied the liver-stages of infection with Plasmodium falciparum and the three-year grant would establish a collaboration between Dr Boddey, Dr Rhoel Dinglasan from the Johns Hopkins Bloomberg School of Public Health, USA, and Dr Philipp Jost from the Technical University of Munich, Germany. Dr Boddey said the research team would study the proteins involved in the clinically silent liver-stage of infection.

"The parasites develop in the liver without eliciting much of an immune response," Dr Boddey said.

"Studies that have disarmed the liver-stage parasite through genetic mutation allowed the immune system to kill the parasites, which provided protective immunity against subsequent infection," Dr Boddey said. "Identifying proteins involved in the liver-stage of malaria is therefore very important for developing potential vaccines."

WEHI said the head of its immunology division Prof Phil Hodgkin would also collaborate on a \$US1.35 million Human Frontier Science Program research grant led by Prof Ton Schumacher from the Netherlands Cancer Institute in association with Prof Andrew Cohen from the University of Wisconsin Milwaukee and Dr Ken Duffy from the National University of Ireland, Maynooth to trace single blood cells from their early stages of development to unravel the cellular and molecular mechanisms that control cell fate.

The Institute said that Human Frontier Science Program research grants were awarded for innovative research projects that involve extensive collaboration among teams of independent scientists working in different countries and in different disciplines.

REVA MEDICAL

The Minneapolis, Minnesota-based Medtronic says it has increased its substantial holding in Reva from 1,298,828 US shares (3.95%) and 957,000 Chess depositary interests (CDIs) (2.95%) to 379,651 US shares (1.10%) and 2,255,828 CDIs (6.80%).

In a separate notice, Reva provided different CDI figures of 9,570,000 and 22,558,280 CDIs, respectively with the previous holding calculated at 6.8 percent and the present holding equivalent to 8.0 percent. There are 10 CDIs to each US share.

Medtronic said it bought 379,651 US shares for \$US2,000,001 (\$A1,901,103) or \$A5.0075 a share on March 23, 2012.

In separate filings, Reva filed substantial shareholder notices for the privately negotiated transactions announced last week to buy \$US24 million of shares of common stock from existing shareholders (BD: Mar 19, 20, 2012).

Reva said the majority of transactions had been completed, with \$US17.6 million closed and a further \$US6.4 million pending.

Reva said that Elliott Associates became a substantial shareholder with 2,005,631 US shares or 6.1 percent.

Reva said that Domain Partners has reduced its substantial holding from 5,386,905 US shares or 16.3 percent to 3,691,188 US shares or 11.2 percent.

Reva said that Saints Capital Everest reduced its substantial holding in Reva from 4,486,556 US shares (13.5%) and 909,091 Chess depositary interests (CDIs) (0.3%) to 3,223,513 US shares (9.7%).

Reva fell one cent or 1.6 percent to 60 cents.

GI DYNAMICS

M&G Investment Funds says its substantial holding is 30,851,583 Chess depositary interests or 10.98 percent of the company.

The London-based M&G group said that today's notice was "a late initial notification due to incorrect market data".

M&G bought shares between September 7, 2011 and March 13, 2012 with two large acquisitions of 13,250,000 shares for \$14,575,000 or \$1.10 a share and 14,500,000 shares for \$12,640,230 or 87.2 cents a share on those two dates, respectively.

GI was up three cents or 3.1 percent to \$1.00.