



# Biotech Daily

Monday September 9, 2013

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH UP: GI DYNAMICS UP 9%; STARPHARMA DOWN 8%**
- \* **UK DIABETOLOGISTS FUNDS GI DYNAMICS ENDOBARRIER TRIAL**
- \* **FDA APPROVES NEUREN PHASE II NNZ-2566 FRAGILE X TRIAL**
- \* **BSI SUBMITS TISSUE THERAPIES VITROGRO DOSSIER TO EMA**
- \* **S&P ASX300 PROMOTES MAYNE, DEMOTES PHARMAXIS**

## MARKET REPORT

The Australian stock market was up 0.71 percent on Monday September 9, 2013 with the S&P ASX 200 up 36.5 points to 5,181.5 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 10 fell, 10 traded unchanged and five were untraded.

GI Dynamics was the best, up seven cents or 9.3 percent to 82 cents with 706,784 shares traded.

Cellmid climbed 7.1 percent; Phylogica was up 6.7 cents; Neuren was up 5.3 percent; QRX was up 4.1 percent; Psivida was up 3.5 percent; Alchemia, Living Cell, Mesoblast, and Tissue Therapies rose more than two percent; Acrux, Clinuvel, Genetic Technologies and Universal Biosensors were up more than one percent; with Cochlear and Medical Developments up by less than one percent.

Starpharma led the falls, down nine cents or 8.4 percent to 98 cents with 389,437 shares traded.

Benitec, Pharmaxis and Reva lost more than three percent; Nanosonics shed 2.3 percent; Optiscan, Phosphagenics and Prana were down more than one percent; with Bionomics, CSL, Heartware, Resmed and Sirtex down by less than one percent.

## GI DYNAMICS

GI Dynamics says the Association of British Clinical Diabetologists has begun an open label clinical trial of its Endobarrier in patients with obesity and type 2 diabetes.

GI Dynamics said the 72-patient multi-center, randomized, controlled 'Revise-Diabetes' study would be funded by the Association of British Clinical Diabetologists Diabetes Care Trust and was supported by the UK National Health Service.

GI Dynamics chief executive officer Stuart Randle said the Association was "a highly prestigious clinical organization in the global diabetes community".

"It is extremely gratifying that they have chosen to invest their own charitable funds in an independent clinical study of our innovative medical device in patients in the UK who are suffering from type 2 diabetes and obesity," Mr Randle said.

Mr Randle said the company was hopeful the study would "help establish Endobarrier therapy as a routine part of diabetes treatment under the NHS".

The company said the study was centered at Birmingham's City Hospital with supporting centers at London King's College Hospital and Guy's and St Thomas' Hospitals and the Glasgow Royal Infirmary in Scotland.

GI Dynamics said the 12-month trial would enroll 72 subjects with type 2 diabetes and obesity who had been treated with the Novo Nordisk injectible drug liraglutide for at least six months, but were sub-optimally-controlled.

The company said that 24 subjects would be treated with the Endobarrier duodenal liner, 24 would receive the Endobarrier with liraglutide and the control group of 24 subjects would have liraglutide alone and all patients would be followed-up for a further 12 months.

GI Dynamics said that the primary endpoints were weight and the blood sugar measure for diabetes, HbA1c.

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## NEUREN PHARMACEUTICALS

Neuren says the US Food and Drug Administration has approved a 60-patient phase II clinical trial of NNZ-2566 in patients with Fragile X syndrome.

Neuren said it intended to begin the trial before the end of 2013.

The company said that adolescent and adult males would be enrolled in a double-blind, placebo-controlled study, which would test two dose levels of NNZ-2566.

Neuren said that preparations for the study, including clinical site qualification and selection, were underway with enrolment expected to be completed by the end of 2014, and top-line results available by July 2015.

Neuren chief scientific officer Larry Glass said that Fragile X syndrome was the fourth investigational new drug (IND) application for NNZ-2566, following traumatic brain injury, concussion and Rett syndrome.

"The approval of the IND for Fragile X Syndrome reinforces our strategy to expand the use of NNZ-2566 in both acute and chronic indications," Mr Glass said.

"It directly supports our approach of bringing a potentially life-changing medicine to patients and maximizing value for our shareholders," Mr Glass said.

Neuren said that NNZ-2566 was a synthetic analogue of a naturally occurring neuropeptide derived from insulin-like growth factor 1 (IGF-1), a growth factor produced by brain cells.

The company said that in animal models, NNZ-2566 inhibited neuro-inflammation and normalized the function of microglia with consequent improvements in molecular, cellular, anatomic and behavioral outcomes.

Neuren was up half a cent or 5.3 percent to 10 cents with 4.9 million shares traded.

## TISSUE THERAPIES

Tissue Therapies says the British Standards Institute has submitted the Vitrogro dossier to the European Medicines Agency for final review for Conformité Européenne (CE) mark. Tissue Therapies said the review by the EMA of manufacturing quality data was the last step in the CE mark approval process, to allow of sales of the Vitrogro ECM wound treatment throughout the European Union.

The company said that the data review was a desk audit, with no onsite inspections.

Tissue Therapies said that during the EMA review it would continue to work with key clinical opinion leaders and on optimizing health economic and reimbursement data to maximize the sales launch as soon as CE mark was granted.

Tissue Therapies chief executive officer Dr Steven Mercer told Biotech Daily that the EMA had 210 days to conclude the review but the EMA could expand the time frame with clock stop for questions.

Dr Mercer said he expected approval by July 2014.

Tissue Therapies was up one cent or 2.9 percent to 35 cents.

## MAYNE PHARMA GROUP, PHARMAXIS

Standard & Poor's Financial Services Dow Jones Indices has promoted Mayne Pharma into and removed Pharmaxis from the ASX300.

No biotechnology companies have been changed in the S&P ASX200.

Mayne was up one cent or 1.7 percent to 58.5 cents.

Pharmaxis fell half a cent or 3.6 percent to 13.5 cents.