



# Biotech Daily

Friday March 10, 2017

*Daily news on ASX-listed biotechnology companies*

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## MARKET REPORT

The Australian stock market was up 0.6 percent on Friday March 10, 2017, with the ASX200 up 34.4 points to 5,775.6 points.

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

Living Cell was the best, up one cent or 9.5 percent to 11.5 cents with 653,065 shares traded.

Dimerix climbed 8.3 percent; Cyclopharm was up 7.5 percent; Reva improved 5.3 percent; Nanosonics and Sirtex were up four percent or more; Cellmid and Factor Therapeutics were up more than three percent; CSL, Genetic Signatures, Oncosil and Opthea rose more than two percent; Airxpanders, Pharmaxis and Viralytics were up more than one percent; with Cochlear, Compumedics, Impedimed, Osprey and Resmed up by less than one percent.

IDT led the falls for the second day in a row, down half a cent or 3.85 percent to 12.5 cents with one million shares traded.

Acrux, Benitec, Polynovo and Starpharma lost more than three percent; Ellex shed 2.2 percent; with Admedus, Bionomics, Medical Developments, Neuren and Pro Medicus down by less than one percent.

## DR BOREHAM'S CRUCIBLE: NEUREN PHARMACEUTICALS

By TIM BOREHAM

**ASX code:** NEU

**Market cap:** \$143 million

**Share price:** 7.9 cents

**Shares on issue:** 1.84 billion

**Executive chairman:** Dr Richard Treagus

**Board:** Dr Richard Treagus, Dr Trevor Scott, Bruce Hancox, Larry Glass

**Financials (2016 calendar year):** operating revenue \$1.49 million (previously \$3.1 million), loss of \$12.01 million (previously \$3.34 million); and cash burn \$12.37 million (\$12.73 million). Cash on hand \$5.05 million (\$16.64 million)

**Shareholders\*:** Lang Walker 19%, Cameron Richard Pty Ltd 4%, Essex Castle 2.6%, Larry Glass 1.13%, Trevor Scott 1.13%.

\*As of April 2016 annual report.

In the tortuous path to drug development it helps to have a plan B under your tiff and possibly a plan C, D and E.

Just like the Cat in the Hat, the New Zealand-originated, Melbourne-based, developer of remedies for hard-to-treat neurological disorders has more than one trick under its headwear - and that's just as well.

A year ago, investors were focused on a program called Intrepid to treat traumatic brain injury (TBI), which was heavily backed by the US Department of Defense (a leading causative agent of such afflictions).

However a 260-patient clinical trial of Neuren's anti-inflammatory compound trofinetide failed to demonstrate a difference between the drug and placebo on three core efficacy measures.

While it's not necessarily curtains for Intrepid - more on that below - Neuren and the military top brass have agreed to put the program on hold for the time being.

Since then the market's attention has turned to using Neuren's lead compound trofinetide (formerly NNZ-2566) to treat Rett syndrome and the rare Fragile X syndrome in paediatric and adult patients.

A form of autism, Rett syndrome affects one in 10,000 females and is characterized by intellectual disability, loss of motor control and muscle rigidity.

A 56-patient phase II study (ranging from 16 to 45 years of age) cited “clinical improvement” as well as passing the usual safety measures.

Investors now await the top-line results from a 62-patient, US-based study of girls aged five years to 15 years.

The idea here is to assess longer-term treatment in a younger cohort, based on similar endpoints to the 56-patient study.

Neuren says: “The primary endpoint for the trial in this younger population is the safety and tolerability of trofinetide compared with placebo.”

“In addition, a number of outcome measures have been included in the study design in order to provide meaningful insights into the efficacy of trofinetide in younger subjects.”

Results are only a few sleeps away (that is, scheduled for some time in March).

In the case of Fragile X, a phase II study involving 70 patients aged between 12 and 45 years pointed to similar clinical improvement.

A follow-up trial is slated next year, for kids between three years and 12 years of age.

Fragile X is an inherited chromosome mutation known as a cause of autism. It affects one in 4,000 males and one in 6,000 females.

As for traumatic brain injury, Intrepid failed its primary endpoints.

But the results were deemed to be “clinically significant” when it came to patients with severe TBI who completed the RBANS test.

The globally-accepted Repeatable Battery for the Assessment of Neuropsychological Studies (RBANS) tests for cognitive impairment on five scores and is especially relevant for dementia patients.

The trial design may also have played a part in the disappointing results.

Neuren argues the under the random allocation between the drug and placebo groups, harder to treat patients were assigned to the former. Discussions continue on a more targeted population, using the RBANS test as a key endpoint.

Why didn't they do that in the first place?

By the way, the peptide trofinetide is a synthetic derivative of glypromate (not to be consumed with the weed-killer glyphosate).

Trofinetide helps restore equilibrium in the brain and arrest neuro-inflammation.

Neuren's latest variant, NNZ-2591, is from the same class of peptides but with higher “bioavailability”.

## **Prospects:**

As auditor PricewaterhouseCoopers diligently pointed out at the half year, Neuren faces “material uncertainty” if it can’t find more of the folding stuff.

With a \$5.1 million end-of-year cash balance compared with \$16 million previously, nothing has changed.

But like the Fat Controller, management has a few levers to pull.

Firstly, it is “actively engaged” in discussions with potential commercial partners.

Secondly, Neuren also has a deep-pocketed shareholder in property developer Lang Walker.

Last year, the board gained shareholder assent to allot 100,000,000 shares to Walker at or above the prevailing share price, if the action is deemed “necessary and in the best interests of shareholders” and if Mr Walker agrees.

This arrangement, valid until June 30, implies a cash injection of \$8 million.

The Rett syndrome trial is helped along by a \$1.3 million grant from the support group rettsyndrome.org

## **Dr Boreham’s diagnosis:**

Neuren is ably-led by Dr Richard Treagus, who built roll-on testosterone outfit Acrux to a \$730 million concern before an unfortunate case of share detumescence set in.

Neuren shares have seen better days, having peaked at 70 cents in early 2005 and having traded between four cents and 12 cents over the last 12 months.

At current levels, Neuren is a punt on decent results this month and/or the partnering or licencing discussions bearing fruit.

Bell Potter estimates the Rett syndrome market at \$US6.1 billion, assuming an annual per-patient reimbursement of \$US125,100 per patient.

The Fragile X market is estimated at \$US8.7 billion in the US alone.

Trofinetide has “orphan drug” status in the US and Europe, which should make for quicker approval

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Such is the burden of proof in a court of law, he has never been found guilty of any indictable offences involving professional misrepresentation.***

## S&P DOW JONES INDICES

Standard & Poor's Dow Jones Indices say they have demoted Sirtex from the S&P ASX100, promoted six biotechnology companies to the All Ordinaries and demoted five. Standard & Poor's said that Airxanders, Cogstate, Compumedics, Ellex Medical Lasers, Innate Immunotherapeutics and Resapp Health had been promoted into the All Ordinaries Index, with Acrux, Admedus, Neuren and Prima removed.

Standard & Poor's said that the changes would take effect from the open of trading on March 20, 2017.

A Standard & Poor's executive told Biotech Daily that the inclusions and removals reflect market capitalization, with the All Ordinaries Index rebalanced annually.

Biotech Daily's Top 40 Index uses different parameters including interesting and good science; preferably, but not necessarily, Australian invented or developed technologies; benefit for human health; quality of board and management; likelihood to result in commercialization; with market capitalization the last consideration.

## ANALYTICA

Analytica says it has issued 44,117,647 shares at 0.68 cents a share to an institutional and sophisticated investor, raising \$300,000.

In January, Analytica said it expected to raise \$1,442,000 in a series of conditional placements at 0.59 cents a share (BD: Jan 31, 2017).

Analytica said at that time that the first placement for \$383,000 would be made to an entity associated with chairman Dr Michael Monsour, subject to shareholder approval and if approved Inov8 LLC would buy \$277,000 in shares, along with a \$60,000 placement was proposed for an entity associated with executive director Mr Ross Mangelsdorf, subject to shareholder approval and a \$722,000 placement to non-related parties.

Analytica said the funds would be used for working capital.

Analytica was up 0.05 cents or 8.3 percent to 0.65 cents.

## NUHEARA

Nuheara says it has received \$412,166 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Nuheara said that the funds related to expenses in the year to June 30, 2016.

Nuheara fell half a cent or 4.55 percent to 10.5 cents with three million shares traded.

## MAYNE PHARMA GROUP

The Melbourne-based Yarra Funds Management says it has become a substantial shareholder in Mayne Pharma with 75,317,673 shares or 5.01 percent.

Yarra Funds said co-holders included AA Australian Finco Pty Ltd, TA SP Australia Topco Pty Ltd and TA Universal Investment Holdings, with registered holders HSBC Custody Nominees, UBS Nominees, JP Morgan Chase Bank, State Street Australia, National Australia Bank, National Nominees, Invia Custodian, BNP Paribas, Citigroup and Northern Trust.

The substantial shareholder notice said that Yarra Funds bought and sold shares between January 13 and March 7, 2017 at prices ranging from \$1.246 to \$1.475.

In January Yarra Yarra Funds Management said it became a substantial shareholder in Sirtex with 3,803,242 shares or 6.59 percent (BD: Jan 22, 2017).

Mayne Pharma fell three cents or 2.3 percent to \$1.295 with 11.8 million shares traded.

## AVITA MEDICAL

Hunter Hall Investment Management says it has reduced its substantial shareholding in Avita from 118,824,372 shares (17.66%) to 111,311,698 shares (16.54%).

The Sydney-based Hunter Hall said that from November 17, 2016 to March 8, 2017 it sold shares with the single largest sale 1,500,000 shares for \$167,118 or 11.1 cents a share. Avita was unchanged at 10 cents.

## MMJ PHYTOTECH

The Toronto, Ontario New York MM Asset Management says it has ceased its substantial holding in MMJ Phytotech selling 5,000,000 shares at 37 cents each.

In February MM said it became a substantial shareholder in MMJ Phytotech with 9,652,632 shares (5.04%), buying the shares at 20.84 cents a share, when the company was trading around 27 cents (BD: Feb 8, 2017).

MMJ was up 8.5 cents or 21.2 percent to 47.5 cents with 16.1 million shares traded.

## NOVOGEN

Novogen says chief scientific officer Dr David Brown, North America chief executive officer Dr Andrew Heaton and chief financial officer Cristyn Humphreys have resigned.

Novogen said that Dr Brown and Dr Heaton were “leaving to explore a planned new venture in early-stage drug discovery” and “separately [Ms Humphreys had resigned] to assume a new role outside the industry”.

All three executives were appointed following the return of Novogen founder Dr Graham Kelly (BD: Dec 7, 2012; May 7, 2013)

In July 2015, Novogen replaced Dr Kelly with director Iain Ross as interim chief executive officer later appointing Dr James Garner as its full-time chief executive officer (BD: Jul 1, 22; Dec 10, 2015).

In 2012, Dr Kelly returned to the company he founded, having resigned as chief executive officer in 2006 (BD: Oct 30, 2006; Dec 7, 2012).

Today, the company said the changes “support the transformation of Novogen from a discovery research organisation to one focused on clinical development, with GDC-0084 preparing for phase II and Cantrixil now in phase I trials”.

Novogen said that over the past nine months it had recruited chief medical officer Dr Gordon Hirsch, chief business officer Dr Peng Leong and director of chemistry, manufacturing and controls David Cain.

Dr Garner said that “David and Andrew were effectively among the founders of Novogen in its current form and their contribution to the company over time has been substantial”.

“They have been instrumental in moving us forward and transforming Novogen to a point where Cantrixil is now in a phase I clinical trial,” Dr Garner said.

“Cristyn Humphreys has made a vital contribution in helping to navigate Novogen through an eventful few years,” Dr Garner said.

Novogen said it would begin a search for a replacement senior financial leader, overseen by company secretary Kate Hill.

Novogen fell 0.7 cents or 8.6 percent to 7.4 cents with 1.8 million shares traded.