# Biotech Daily

Monday March 19, 2018

*Daily news on ASX-listed biotechnology companies*

*** ASX, BIOTECH UP: CYCLOPHARM UP 9%; IMMUTEP DOWN 8%**

*** PATRYS: 'PAT-DX1 IMPROVES GLIOBLASTOMA SURVIVAL IN MICE'**

*** BLUECHIIP'S ANDREW MCLELLAN: 'STRATEGY CHANGE IS PAYING OFF'**

*** SOMNOMED RETAIL OFFER RAISES $4.5m, TOTAL $10.4m**

*** AVITA STARTS CHINA RECELL BURNS TRIAL**

*** CLINUVEL 13-MONTH DATA BACKS SCENESSE FOR EPP**

*** MEMPHASYS SETTLES PLATINUM ROAD, BRIDGE ROAD CAPITAL FIGHT**

*** OPTISCAN SPILL GROUP HOLDS 13.4%**

*** HYDROPONICS EGM SIMPLIFIES AGM**

*** ORTHOCELL APPOINTS PROF MASSIMO SIMION ADVISOR**

*** INVICTUS APPOINTS DR DAVID KINGSTON ADVISORY BOARD CHAIR**

*** MARK LICCIARDO, KATE GOLAND REPLACE AVITA'S GABRIEL CHIAPPINI**

*** AUSTRALIAN ETHICAL TAKES 7% OF IMMUTEP**

## MARKET REPORT

The Australian stock market was up 0.17 percent on Monday March 19, 2018, with the ASX200 up 10.0 points to 5,959.4 points. Nineteen of the Biotech Daily Top 40 stocks were up, 13 fell, six traded unchanged and two were untraded.

Cyclopharm was the best, up 9.5 cents or 8.6 percent to $1.195 with 20,466 shares traded. Bionomics and Universal Biosensors climbed six percent or more; Clinuvel, Compumedics, Osprey and Telix improved more than four percent; Acrux, Avita and Prana were up more than three percent; Neuren, Optiscan, Polynovo and Reva rose two percent or more; Actinogen, Impedimed, Resmed and Uscom were up more than one percent; with CSL, Psivida and Sirtex up by less than one percent.

Immutep led the falls, down 0.2 cents or eight percent to 2.3 cents with 23.1 million shares traded. Airxpanders, Pharmaxis and Starpharma lost five percent or more; Dimerix, Genetic Signatures, Medical Developments and Volpara were down more than three percent; Mesoblast, Nanosonics, Opthea and Orthocell shed more than one percent; with Cochlear and Ellex down by less than one percent.

PATRYS

Patrys says that mice treated with its PAT-DX1 in a model of glioblastoma survived a statistically significant 20.8 percent longer than untreated controls.

Patrys said that with seven mice in each study arm, mice treated with PAT-DX1 showed a median survival of 87 days, compared to controls that survived a median of 72 days.

The company said that mean survival data reflected the trend, with 83 days (plus or minus 3.2 days) for PAT-DX1 treated mice, and 71 days (plus or minus 1.2 days) for the controls ($p = 0.004$).

Patrys said that no toxicity associated with PAT-DX1 treatment was observed.

The company said that the study also evaluated the performance of the poly adenosine diphosphate ribose polymerase (PARP) inhibitor olaparib (marketed as Lynparza) and a combination of olaparib and PAT-DX1 in the same model of glioblastoma.

Patrys said that PAT-DX1 alone was superior to olaparib alone and the addition of olaparib to PAT-DX1 did not yield any significant improvement over PAT-DX1 alone.

The company said that the results were likely to reflect “the limited ability of olaparib to cross the blood brain barrier and they reinforce the need for methods in neuro-oncology to help deliver therapeutics such as olaparib across the blood brain barrier to treat malignancies of the central nervous system”.

In February, Patrys said that an earlier part to the study at Yale University by Dr James Hansen and Dr Jiangbing Zhou showed that PAT-DX1 crossed the blood-brain barrier, significantly reducing glioblastoma tumor in the brains of mice (BD: Feb 28, 2018).

Today, the company said it was developing nanoparticles conjugated to PAT-DX1, known as PAT-DX1-NP, which had been shown to enhance targeting to brain tumors in mice.

Patrys said that PAT-DX1-NP could be loaded with therapeutics that otherwise would have limited access to brain tumors, so PAT-DX1 had the “potential to be used against brain tumors both as a single agent and as a delivery vector to help transport drug-loaded nanoparticles across the blood brain barrier”.

The company said that a key prognostic marker in glioblastoma was the methylation status of the promoter for DNA repair gene MGMT, with methylated MGMT predictive of a better response to temozolomide and improved survival, while MGMT-unmethylated glioblastoma had a worse prognosis and was more difficult to treat.

Patrys said that Dr Hansen and Dr Zhou had shown that PAT-DX1 administered by tail vein injection significantly improved survival in an orthotopic animal model of MGMT unmethylated glioblastoma derived from human tumor explants.

Patrys chief executive officer Dr James Campbell said that “the observation that PAT-DX1 enhanced survival of animals with MGMT-unmethylated glioblastoma is significant and a positive signal for Patrys’ ongoing pre-clinical research”.

“The result is consistent with the previously described observation that PAT-DX1 crossed the blood-brain barrier and significantly reduced tumor size in the same animal model of glioblastoma,” Dr Campbell said.

“Patrys believes that this model, based on human tumor explants, is one of the best animal models for glioblastoma, and is encouraged by these data that show that PAT-DX1 has single agent activity against glioblastoma with no apparent toxicity,” Dr Campbell said.

Dr Campbell said the company was continuing pre-clinical work to optimize dosing and scheduling of PAT-DX1 in a range of cancers, as wellas pre-manufacturing activities.

Patrys said that PAT-DX1 was a humanized version of Deoxymab 3E10 which penetrated into the cell nuclei and bound directly to DNA where it inhibited DNA repair processes and killed cells that had mutations or deficiencies in DNA repair mechanisms as found in various cancer cells.

Patrys climbed half a cent or 9.3 percent to 5.9 cents with 161.9 million shares traded.

## BLUECHIIP

Bluechiip chief executive officer Andrew McLellan is confident the change of marketing strategy is paying off and despite patchy revenue increasing, sales are on the way.

When Mr McLellan was appointed chief executive officer of Bluechiip he moved from trying to sell the micro-electron mechanical system (MEMS) tags for sample storage and monitoring to individual companies to attach to their cryogenic, or deep frozen, blood and tissue sample tubes, to selling directly to the companies which made the tubes to incorporate the tags.

The first major customer was the San Francisco-based Labcon North America which has placed orders and is receiving the Bluechiip tags and readers.

Mr McLellan said the company had dispatched 24,000 tags in December and 80,000 between the start of January and today.

“And we have orders in hand for volumes to build over the year,” Mr McLellan said.

“The order with Labcon is non-exclusive so we expect to sign more contracts,” Mr McLellan said.

He said the company has orders worth more than $1 million in total for the provision of the cryogenic readings systems over a period of about 12 months.

“The orders are for monthly cycles but we don’t expect it to stop at the end of the order,” Mr McLellan said.

“We expect further orders for larger quantities,” Mr McLellan said.

Mr McLellan said there was “a bit of work” to go before the company would be cash-flow positive or break-even.

“We may need more capital in the future but we expect to deliver further on milestones such as delivery of chips and readers, entering manufacturing and distribution deals and further customer contracts,” Mr McLellan said.

According to the company’s Appendix 4C quarterly reports, receipts from customers increased from $27,000 for the three months to March 31, 2017 to $111,000 for the three months to June 30, $155,000 for the three months to September 30, but fell to $69,000 for the three months to December 31, 2017.

Bluechiip reported receipts from customers for the six months to December 31, 2016 of $124,225, compared to $11,183 for the six months to December 31, 2015.

Bluechiip was unchanged at 6.1 cents.

## SOMNOMED

Somnomed says its retail one-for-17 entitlement offer at $3.00 a share has raised about $4.47 million taking the total raised to $10.4 million.

In February, Somnomed said that its institutional entitlement offer, on the same terms, raised $5.9 million (BD: Feb 21, 2018).

Today, the company said that about 62 percent of available retail entitlements were taken-up under the offer, the 20 percent institutional shortfall had been placed and the 38 percent retail shortfall would be placed to TDM Asset Management and other existing shareholders who participated in the institutional offer and had indicated their interest to acquire additional shares.

Somnomed said the funds would provide working capital to continue the rollout of its direct-to-patient obstructive sleep apnoea model through its Renew Sleep Solutions centres in North America.

Somnomed was up five cents or 1.6 percent to $3.20.

## AVITA MEDICAL

Avita says it has begun a 220-patient randomized, controlled clinical trial of Recell for the treatment of deep partial-thickness, or second-degree, burns in China.
Avita said the trial, titled: 'Key Technique and Clinical Pathway for Burn Treatment' was funded by the China National Health and Family Planning Commission and would be led by Dr Dahai Hu of the First Affiliated Hospital of the Fourth Military Medical University.
The company said that burn patients would be randomized to either standard of care, Recell or one of two other treatments and take about 18 months.
Avita said it would collaborate with the plastic surgery department of Peking Union Medical College Hospital to establish a Recell training centre in Beijing to help standardize the protocols for the use of Recell, train Recell surgeons country wide and encourage the expansion of Recell to hospitals across China.
The company said that Recell was being distributed in China by state-owned healthcare group China Pharmaceutical Group Shanghai Medical Instrument Co.
Avita chief executive officer Dr Michael Perry said the company's "initiatives within China are consistent with our evolving strategy of using data from controlled clinical trials and health economic studies to ensure that Recell is effectively promoted and priced in all major markets".
The company said that it expected to begin additional clinical trials in burns patients in Australia and the UK this year, as well as two US controlled, paediatric trials.
The company said the China and US Government support allowed the trials and other Recell initiatives "to be accelerated while maintaining resource requirements at a reasonable level".
Avita was up 0.2 cents or 3.4 percent to 6.1 cents with 5.3 million shares traded.

## CLINUVEL PHARMACEUTICALS

Clinuvel says 13-month data shows an unchanged safety profile for Scenesse for erythropoietic protoporphyria and nearly all patients continuing treatment.
Clinuvel said that 61 percent of patients had no previous exposure the Scenesse and 99 percent continued treatment, with requests for a paediatric formulation.
The company said that specialist porphyria doctors and medical staff from 12 European countries and 21 centres attended its third European meeting in Vienna, on March 16, 2018 to discuss the ongoing treatment of adult patients with erythropoietic protoporphyria (EPP), the post-authorization obligation for collection of data and the clinical relevance of the treatment with Scenesse (afamelanotide16mg).
Clinuvel said it was required to conduct a post-authorisation safety study as agreed with the European Medicines Agency, capturing data on the ongoing safety and use of Scenesse in adult patients participating in the European EPP Disease Registry.
The company said that the general observations were that Scenesse "provided therapeutic value under real-world conditions and that it enabled EPP patients to engage in daily activities which had not been previously possible".
Clinuvel said that 16 percent of patients sought treatment during the autumn and winter months and medical staff from the centres said that that a higher number of parents and carers had requested afamelanotide treatment for children diagnosed with EPP since the treatment for adults had been made available.
The company said it would discuss suggested changes with the European Medicines Agency, in particular to widen the recommended maximum dose of Scenesse per year.
Clinuvel was up 41 cents or 4.3 percent to $9.99 with 108,959 shares traded.

## MEMPHASYS

Memphasys says it has settled the legal action with former financiers, Platinum Road Pty Ltd and its related entity, Bridge Road Capital Pty Ltd.
In February, Memphasys said that Platinum Road and Bridge Road Capital had named it as a defendant in a Supreme Court of Victoria writ and it intended to take all necessary action to defend the claim (BD: Feb 13, 2018).
Today, the company said that the settlement provided for a cash payment by Memphasys to Platinum Road and Bridge Road Capital, “but the settlement amount is not considered material and is confidential”.
Memphasys was unchanged at 0.2 cents with 1.2 million shares traded.

## OPTISCAN IMAGING

Optiscan shareholders including former chief executive officer Archie Fraser who have called for a board spill, say they hold 57,817,204 shares or 13.41 percent of the company.
Last week Optiscan said the board spill was called by Ibsen Pty Ltd (the Narula family), company founder and inventor Peter Maxwell Delaney, Archie Fraser Pty Ltd and IT IS Consulting Pty Ltd (Wymant family) (BD: Mar 16, 2018).
Today, the name Ezahc Pty Ltd was added to the substantial shareholder notice which said the association was to move resolutions to remove chairman Alan Hoffman and directors Peter Francis, Dr Ian Griffiths and Dr Philip Currie, to be replaced by Mr Fraser and Ron Grey.
Optiscan director Ian Mann is a director of Ibsen and Ezahc.
Optiscan was up 0.2 cents or 2.8 percent to 7.4 cents.

## THE HYDROPONICS COMPANY

Hydroponics says that following last week’s extraordinary general meeting, five resolutions have been removed from its annual general meeting (BD: Mar 16, 2018).
Hydroponics said that the meeting would vote on the remuneration report and the election of chairman Steven Xu and directors Alan Beasley, Lou Cattelan and Gary Radcliff, but not the re-election or appointment of former directors of Ian Mutton, Mary Verschuer, Peter Wallace and Hamish MacDonald, and former chief executive officer David Radford would not be standing for elections.
The annual general meeting will be held at the Function Centre, Level 4, 60 Carrington Street, Sydney, on March 23, 2018 at 11am (AEDT).
Hydroponics fell 4.5 cents or seven percent to 59.5 cents.

## ORTHOCELL

Orthocell says it has appointed Prof Massimo Simion to its medical and scientific advisory board to drive its Celgro scaffold into the European market.
Orthocell said that Prof Simion was an oral surgeon, specializing in periodontics and dental implant surgery with more than 100 articles published in scientific journals.
The company said that Prof Simion was the chairman of the University of Milan’s Department of Periodontology and Implant Restoration, and a founder of the Italian Society of Osseointegration.
Orthocell said it would make further appointments to board.
Orthocell fell half a cent or 1.7 percent to 28.5 cents.

## INVICTUS BIOTECHNOLOGY

Invictus says it has appointed Dr David Kingston as the chair of its scientific advisory board.

Invictus said that Dr Kingston was formerly the medical director of Roche Australia where he was involved in all product lifecycle phases from phase I to IV including clinical development, regulatory, Pharmaceutical Benefits Scheme listing and medical affairs for more than 40 new products.

Invictus executive chairman Dr Glenn Tong said that Dr Kingston had been “an integral part of the team that developed Invictus Biotechnology’s assets to date and we are looking forward to continuing to benefit from his extensive experience in product development as we launch our two dietary supplement products in the US and progress our clinical development program with two novel delivery platforms”.

Invictus said it was working with Dr Kingston to recruit the rest of the scientific advisory board.

Invictus is a private company.

## AVITA MEDICAL

Avita says that Mertons Corporate Services Mark Licciardo and Kate Goland have been appointed as joint company secretaries replacing Gabriel Chiappini, effective today.

## IMMUTEP

Australian Ethical Investment says it has become a substantial shareholder in Immutep with 202,380,952 shares or 7.43 percent.

Australian Ethical said that on March 14, 2018 it bought the 202,380,952 shares for $4,250,000 or 2.1 cents a share.

Immutep fell 0.2 cents or eight percent to 2.3 cents with 23.1 million shares traded.