# Biotech Daily

Monday February 6, 2017

*Daily news on ASX-listed biotechnology companies*

*** ASX, BIOTECH DOWN: COMPUMEDICS UP 12%, LIVING CELL DOWN 20%**

*** CYCLOPHARM EXPECTS RECORD REVENUE UP 14% TO $14m**

*** CYNATA 60-MOUSE STUDY BACKS CYP-001 FOR GVHD**

*** BIOTRON MOUSE DATA: 'BIT225 REDUCES HIV LOAD FASTER'**

*** IMMURON STARTS PAEDIATRIC IMM-124E FATTY LIVER DISEASE TRIAL**

*** GRAND CHALLENGES CANADA $1.3m LOAN FOR ATOMO**

*** BIOXYNE 'RESETS' 6m DR PETER FRENCH OPTIONS to 3m**

*** NEUROTECH HIRES EMERGO FOR MENTE AUTISM US REGULATION**

## MARKET REPORT

The Australian stock market fell 0.11 percent on Monday February 6, 2017 with the ASX200 down 6.0 points to 5,615.6 points. Eleven of the Biotech Daily Top 40 stocks were up, 15 fell, 11 traded unchanged and three were untraded.

Compumedics was the best, up eight cents or 11.9 percent to 75 cents with 116,536 shares traded.

Neuren and Viralytics climbed more than five percent; Reva was up 4.2 percent; Factor Therapeutics, Orthocell and Pharmaxis were up more than three percent; Anteo rose 2.6 percent; Bionomics and Nanosonics were up more than one percent; with Pro Medicus and Resmed up by less than one percent.

Living Cell led the falls, down 2.5 cents or 20 percent to 10 cents with 710,636 shares traded, followed by Friday's 81.8 percent best, Benitec, down 17.5 percent to 16.5 cents with two million shares traded.

Psivida lost 9.8 percent; Airxpanders and Clinuvel shed more than five percent; Atcor, Cyclopharm and Medical Developments fell more than four percent; Mesoblast and Opthea were down more than three percent; Prima shed 2.9 percent; Cochlear, Ellex, Osprey and Universal Biosensors were down more than one percent; with CSL and Sirtex down by less than one percent.

## CYCLOPHARM

Cyclopharm says unaudited accounts for the 12 months to December 31, 2016 indicate it will report record sales revenue up 14.3 percent to $14.4 million.
Cyclopharm said that the increase in full year revenue was driven by 95 percent higher unit sales of Technegas generators for lung imaging and a 10 percent increase in patient administration sets.
The company said the higher sales of Technegas generators included the company's single largest Technegas order consisting of 50 generators and 250 patient administration sets, valued at $1.38 million from its Chinese distributor as a seeding initiative, which was were expected to provide a platform for significantly higher kit sales in China from 2018.
Cyclopharm said that excluding China, 2016 revenue exceeded the 2015 record result.
Cyclopharm fell four cents or 4.4 percent to 87 cents.

## CYNATA THERAPEUTICS

Cynata says the final report supports its proof-of-concept 60-mouse study of CYP-001 Cymerus mesenchymal stem cells for graft versus host disease.
Cynata said that the report confirmed and extended the findings from the initial study with the data showing a clear and robust therapeutic effect of CYP-001.
The company said that severe acute graft versus host disease (GvHD) was induced by infusing human peripheral blood mononuclear cells into gamma-irradiated mice.
Cynata said that the first stage was a survival study, in which animals were randomly assigned to control or treatment groups, with treated animals receiving either one or two doses of CYP-001, while control animals received only saline.
The company said that as reported last year, the interim results showed that CYP-001 treatment substantially prolonged survival in this model (BD: Apr 7, 2016).
Cynata said the second stage of the study involved additional survival studies with larger numbers of animals to confirm the results of the initial survival study, in addition to a series of analyses at two pre-defined time-points in further cohorts of animals, with the aim of investigating the mechanism of action of CYP-001 in treating this disease.
The company said 60 animals were randomly assigned to six groups, three not GvHD induced, but treated with control, one dose or two doses of CYP-001 and three groups in which GvHD was induced and treated with control, one dose or two doses of CYP-001.
Cynata said that in the non-GvHD groups, all animals remained healthy for the 100-day study period, indicating that CYP-001 treatment did not adversely affect the animals.
The company said that in animals in which GvHD was induced, the control animals survived for a median of 24.5 days, while treatment with CYP-001 "markedly prolonged survival with the median survival time being 48 days and 57 days, respectively, in recipients of a single dose or dual doses of CYP-001", which was statistically significant.
Cynata said that the mechanistic studies generated a substantial body of data, including evidence that CYP-001 treatment significantly decreased the percentage of CD4 and CD8 T-cells infiltrating the bone marrow, considered to be a key driver of GvHD.
The research was supervised by the University of Massachusetts Amherst's Prof Lisa Minter who concluded "either a single- or dual-dose treatment with Cymerus [mesenchymal stem cells] significantly attenuates disease severity and provides a robust survival benefit in our preclinical model of GvHD".
"Furthermore, our analysis of biomarkers provides important insights into the mechanism of action of Cymerus [stem cells] and a framework for monitoring in clinical trials," Prof Minter said.
Cynata was up three cents or five percent to 63 cents.

## BIOTRON

Biotron says an HIV-1 mouse trial shows that the addition of BIT225 significantly reduces HIV-1 viral loads beyond the current best anti-retroviral treatments.

Biotron did not say how many mice were in the study, announced in an annual general meeting presentation, but said BIT225 accelerated the reduction of HIV-1 levels, when compared to combinations without BIT225.

The company said the study was performed in mice whose immune system was replaced with human cells, making them susceptible to infection with HIV-1, and showed the addition of BIT225 to anti-retroviral treatment results in a delayed and slower rate of viral rebound when anti-viral drugs are stopped.

The company said that in addition to a faster, greater reduction of HIV-1 viral load, the study suggested that BIT225 treatment might lead to eradication of a viral reservoir.

Biotron said that following a detailed analysis of the mouse data package, the phase II BIT225-009 clinical trial would be expedited".

Biotron managing-director Dr Michelle Miller said the study "demonstrates that BIT225 attacks a different source of virus than do the current anti-HIV-1 drugs".

"BIT225 has the potential to play a key role in the eradication of HIV-1 by targeting and clearing HIV-1 from certain reservoirs," Dr Miller said.

Biotron was up half a cent or 14.7 percent to 3.9 cents with 6.2 million shares traded.

## IMMURON

Immuron says that Emory University has enrolled the first of 40 paediatric patients in its phase II trial of IMM-124E for non-alcoholic fatty liver disease.

Immuron said that the US National Institutes of Health-funded, double-blind, placebo-controlled, randomized study was designed to assess safety and efficacy after 12 weeks treatment at the Atlanta, Georgia-based Emory University.

The company said that paediatric non-alcoholic fatty liver disease was a progressive form of liver disease associated with excessive fat storage in the liver together with inflammation, which could lead to liver fibrosis and cirrhosis, believed to affect up to 10 percent of US children, with no treatments approved.

Immuron said the mechanism of action was thought to include chronic inflammation from intestinal microbiome-derived products, or lipo-poly-saccharides and metabolites, which passed through the "leaky gut" to the liver where they activated an immune response.

Immuron said that IMM-124E was rich in anti- lipo-poly-saccharides antibodies and would improve insulin resistance and decrease systemic and hepatic inflammation through modulation of bacterial products and the microbiome.

Immuron was unchanged at 30 cents.

## ATOMO DIAGNOSTICS

Atomo says it has received a $US1 million ($A1.31 million) loan from Grand Challenges Canada to support its continued business operations.

The Sydney-based Atomo said that Grand Challenges was funded by the Government of Canada and made two prior investments in the company during the last year.

The company is developing a "affordable, point-of-care and consumer diagnostics" for a range of indications (BD: May 31, Jun 15, Oct 27, Nov 10, 2016).

Atomo said the loan could be converted, at its election, to equity B-class shares, similar to the B-class share raise led by GHIF which closed in July 2016 (BD: Aug 11, 2016).

Atomo is a private company.

## BIOXYNE

Bioxyne says that a resolution to grant scientific director Dr Peter French 6,000,000 options has been reset to 3,000,000 options.

Last year, Bioxyne said that an annual general meeting resolution to grant Dr French 6,000,000 options had been withdrawn from that day's meeting (BD: Nov 24, 2016).

At that time, Bioxyne removed the resolution to grant 1,000,000 class A options, 2,000,000 class B options and 3,000,000 class C options to Dr French, saying it would be "dealt with at a subsequent shareholders meeting" as proposed in the October notice of meeting (BD: Oct 25, 2016).

The notice of meeting said that class A options would be exercisable at 2.34 cents each by November 24, 2019; 40 percent of the class B options vest on achieving 75 percent of the budgeted net profit after tax (NPAT) for 2016-'17 and all vest on reaching that target, exercisable at 2.6 cents a share by November 24, 2020, with 50 percent of the class C options vesting on achieving 75 percent of the budgeted NPAT for 2017-'18 and all vest on reaching that target, exercisable at 3.03 cents a share by November 24, 2021.

Bioxyne did not disclose its budgeted NPAT for either year, but the company's net profit after tax for the 12 months to June 30, 2016 was $223,846 (BD: Aug 31, 2016).

All resolutions to the meeting passed easily (BD: Nov 25, 2016).

Today Bioxyne said that all proposed 3,000,000 options would be exercisable at 2.34 cents each by November 24, 2019, with 1,000,000 subject to shareholder approval and all options to be issued "pursuant to the terms and conditions of the employee share option plan.

Bioxyne was unchanged at two cents.

## NEUROTECH INTERNATIONAL

Neurotech says it has hired the Austin, Texas-based Emergo Group as its US regulatory consultant for its electro-encephalogram-based Mente Autism product.

Neurotech said that Emergo assisted companies with regulatory strategy, device registration, quality management system compliance and in-country regulatory representation.

The company said it would work with Emergo to prepare a pre-submission package to the US Food and Drug Administration, with the aim of conducting a pre-submission meeting with by July 2017.

Neurotech said that the previous Mente 2 device was FDA-listed, and the meeting would introduce Neurotech and the third iteration of the technology Mente Autism to the FDA prior to any formal submissions.

Neurotech fell half a cent or 1.7 percent to 29.5 cents.