# Biotech Daily

**Tuesday February 28, 2017**

*Daily news on ASX-listed biotechnology companies*

*** ASX, BIOTECH DOWN: ADMEDUS UP 9.5%, COMPUMEDICS DOWN 34%**

*** WEHI: 'GENETIC EVIDENCE FOR INCURABLE MACTEL BLINDNESS'**

*** TGA APPROVES CSL'S ZEMAIRA FOR ALPHA-1 ANTITRYPSIN DEFICIENCY**

*** MAYNE TO MARKET MITHRA'S MYRING CONTRACEPTIVE**

*** COMPUMEDICS H1 REVENUE DOWN 7% TO $16m, PROFIT DOWN 88% TO $226k**

*** CELLMID H1 REVENUE UP 56% TO $2.2m, LOSS DOWN 13% TO $1.5m**

*** MEDLAB H1 REVENUE UP 83% TO $2m, LOSS DOWN 1% TO $1.8m**

*** GENENTECH TAKES PHYLOGICA H1 REVENUE TO $3m, LOSS DOWN 39%**

*** PHOSPHAGENICS REVENUE DOWN 27.5% to $1.6m, LOSS DOWN 14% TO $17m**

*** ADHERIUM H1 REVENUE $1.4m, LOSS $1.6m**

*** GI DYNAMICS REVENUE DOWN 59% TO $709k, LOSS DOWN 63% TO $17m**

*** SAUDI ARABIA APPROVES ADMEDUS CARDIOCEL HEART PATCH**

*** INNATE PHASE IIb TRIAL OF MIS416 FOR MS ON-SCHEDULE**

*** MMJ DISTRIBUTOR HL PHARMA APPLIES FOR CANNABIS IMPORT LICENCE**

*** MACQUARIE GROUP BELOW 5% OF MMJ**

*** ALLAN GRAY BELOW 5% OF ACRUX**

*** ONCOSIL APPOINTS DR MARTIN CROSS DIRECTOR**

*** DR PAUL WOTTON REPLACES CYNATA CHAIR DR STEWART WASHER**

## MARKET REPORT

The Australian stock market fell 0.21 percent on Tuesday February 28, 2017 with the ASX200 down 12.0 points to 5,712.2 points. Eleven of the Biotech Daily Top 40 stocks were up, 14 fell, 13 traded unchanged and two were untraded. All three Big Caps fell.

Admedus was the best, up three cents or 9.5 percent to 34.5 cents, with 900,598 shares traded. Viralytics climbed 7.1 percent; Clinuvel and Starpharma improved more than four percent; Nanosonics was up 3.2 percent; Opthea and Uscom rose more than two percent; with Bionomics, Factor Therapeutics, Mesoblast, Polynovo and Pro Medicus up more than one percent.

Compumedics led the falls, down 22.5 cents or 33.8 percent to 44 cents with two million shares traded. Impedimed lost 6.2 percent; Airxpanders and Cellmid retreated more than five percent; Atcor fell 4.55 percent; Neuren and Orthocell shed more than two percent; Acrux, Actinogen, Medical Developments, Osprey and Reva were down more than one percent; with Cochlear, CSL, Ellex, Resmed and Sirtex down by less than one percent.

## THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says its staff have discovered evidence of genes that cause the untreatable degenerative eye disease macular telangiectasia type 2.

WEHI said that macular telangiectasia type 2 was incurable and untreatable and led to blindness.

The Institute said that the team's findings established five key regions, or loci, in the genome most likely to influence a person's risk of developing macular telangiectasia type 2 and the finding would enable researchers to better understand the disease and look for ways to prevent or stop its progression.

WEHI said that the study, entitled 'Genome-wide analyses identify common variants associated with macular telangiectasia type 2', published in Nature Genetics was led by bio-informaticians Prof Melanie Bahlo and Dr Thomas Scerri, with an abstract available at: http://go.nature.com/2lPwEVI.

The Institute said that macular telangiectasia type 2, or Mactel, was "a rare and complex disease" mainly affecting people from the age of 40 years and causing abnormal growth of blood vessels in the macula, in the middle of the retina.

WEHI said that patients lost central vision crucial for tasks requiring focus, such as driving or reading.

Prof Bahlo said the study involved detailed genetic analysis of patients from around the world, including Australia, using genome wide association studies.

"We analysed more than six million genetic markers and identified five regions, called loci, across the genome that had similar patterns in people with the disease, but not the healthy individuals," Prof Bahlo said.

"These five genetic risk loci are our treasure map, telling us where to keep digging in order to discover the specific genes implicated in Mactel," Prof Bahlo said.

WEHI said that Prof Bahlo and her team worked with collaborators in London and New York to analyse the genetic data from 476 people with the disease and 1733 people without the disease.

"We were thrilled when our results were corroborated by two further independent validation studies," Prof Bahlo said.

WEHI said that the analysis showed that people with the Mactel genetic risk loci identified in the study had changes in their metabolism, specifically in their glycine and serine levels. Prof Bahlo said this meant there could be a significant relationship between the level of glycine and serine in the body and onset of the disease.

"Though the exact link between the disease and glycine and serine is yet to be confirmed, the connection is an exciting clue to help us further explore metabolic abnormalities in people with Mactel," Prof Bahlo said.

Dr Scerri said the team's work highlighted crucial points of interest that, with further investigation, could help researchers find a way to prevent the progression of the disease.

"We are continuing to explore the genetic data to try to identify the specific genes involved, and the precise genetic variations that are leading to the disease," Dr Scerri said.

President of the Lowy Medical Research Institute that sponsored the research Prof Martin Friedlander said the work was "a significant advancement in efforts to understand the cause of Mactel.

"We are working to develop treatments effective in preserving vision in patients with this disease," Prof Friedlander said.

## CSL

CSL says the Australian Therapeutic Goods Administration has approved Zemaira for the lung disease alpha-1 antitrypsin deficiency.
CSL said that Zemaira had been proven in a prospective double-blind, placebo-controlled trial to significantly reduce the loss of lung tissue, slowing the progression of emphysema due to alpha-1 antitrypsin deficiency (AATD).
The company said that AATD was a hereditary condition marked by a lack of the alpha-1 antitrypsin protein, whose main function was to protect the lungs from inflammation.
Alpha-1 Association of Australia president Steven Knowles said that patients in Australia had been waiting for 30 years for access to alpha-1 therapy.
"The success of CSL Behring in attaining registration of Zemaira brings broad patient access to this therapy an important step closer to reality," Mr Knowles said.
CSL said that Zemaira was a highly purified alpha-1 proteinase Inhibitor derived from human plasma and the only alpha-1 proteinase Inhibitor proven to significantly reduce the loss of lung tissue, slowing the progression of emphysema due to AATD.
CSL fell seven cents or 0.06 percent to $117.86 with 1.3 million shares traded.

## MAYNE PHARMA GROUP

Mayne Pharma says it has a licence and supply agreement with Mithra Pharmaceuticals SA for its Myring intra-vaginal hormonal contraceptive delivery device.
Mayne said that under the long-term exclusive agreement it would have responsibility to market, sell and distribute the product following US Food and Drug Administration approval, with the Liège, Belgium-based Mithra responsible for supply.
The company said that Myring was a non-biocompatible, flexible ring shape device releasing a combination of etonogestrel and ethinyl estradiol over a three-week period.
Mayne said that Myring was under development by Mithra, which specialized in drugs and therapeutic products for women's health and it expected to file the product with the US Food and Drug Administration this year.
The company said that Myring had been developed to be a generic version of Merck's Nuvaring which had US sales of about $US780 million in 2016.
Mayne chief executive officer Scott Richards said that following the Teva portfolio acquisition the company had become "the second largest supplier of oral contraceptives in the US market and we have been actively seeking complementary portfolio and pipeline product opportunities".
Mayne fell 4.5 cents or three percent to $1.475 with eight million shares traded.

## COMPUMEDICS

Compumedics says revenue for the six months to December 31, 2016, fell 6.7 percent to $16,191,000 with net profit after tax down 87.9 percent to $226,000.
Compumedics said that sales were "very strong" in China but lower in the US and Germany with expected business "not received in the time frame anticipated".
The company said the decline in profit was "primarily a result of the shortfall in sales and shipments and some increased expenses associated with the new growth initiatives".
The company said that net tangible assets per share was up 48.4 percent to 9.2 cents at December 31, 2016, with diluted earnings per share down 90.9 percent to 0.1 cents.
Compumedics said that cash and cash equivalents at December 31, 2016 was $5,721,000 compared to $1,665,000 at December 31, 2015.
Compumedics fell 22.5 cents or 33.8 percent to 44 cents with two million shares traded.

## CELLMID

Cellmid says its revenue for the six months to December 31, 2016 was up 56.4 percent to $2,179,924 with net loss after tax down 12.6 percent to $1,510,541.
Cellmid said most of its revenue was from its Évolis hair loss treatment business with sales up 65.0 percent to $2,007,230 for the six months to December 31, 2016, along with royalties for its Cxbladder midkine-based bladder cancer diagnostic licenced to Pacific Edge Biotechnology and royalties for its midkine Elisa diagnostic kit of $146,586.
Cellmid said that net tangible assets per share was up 11.6 percent to 0.48 cents at December 31, 2016, with diluted loss per share down 15.8 percent to 0.16 cents.
The company said it held cash and cash equivalents of $5,345,308 at December 31, 2016 compared to $4,524,638 at December 31, 2015.
Cellmid fell 0.2 cents or 5.9 percent to 3.2 cents with 5.8 million shares traded.

## MEDLAB CLINICAL

Medlab says its revenue for the six months to December 31, 2016 was up 83.4 percent to $2,123,668 with net loss after tax down 0.8 percent to $1,784,953.
Medlab said that its revenue was primarily $1,482,585 from its food additives, along with $611,325 from pharmaceutical research and its major focus had been on the development of its Nanocelle delivery of cannabis and atorvastatin.
Medlab said that net tangible assets per security was up 20.8 percent to 2.9 cents at December 31, 2016, with diluted loss per share was down 28.0 percent to 0.95 cents.
The company said it had cash and cash equivalents of $4,309,132 at December 31, 2016 compared to $801,368 at June 30, 2016.
Medlab fell 0.5 cents or 0.6 percent to 83 cents.

## PHYLOGICA

Phylogica says that revenue for the six months to December 31, 2016, was up 2,847 percent to $2,800,000 reducing net loss after tax 38.5 percent to $458,000.
Last year Phylogica said that Genentech would pay $US2 million ($A2.75 million) to extend the licence to its Phylomers for antibiotics (BD: Dec 19, 2016).
The company said that diluted loss per share fell 60.0 percent to 0.02 cents, net tangible assets per share was down 40.0 percent to 0.27 cents and it had cash and equivalents of $3,453,368 at December 31, 2016, compared to $7,073,541 at June 30, 2016.
Phylogica was up 0.1 cents or 2.9 percent to 3.6 cents.

## PHOSPHAGENICS

Phosphagenics says revenue for the year to December 31, 2015, fell 27.5 percent to $1,588,000 with net loss after tax down 13.9 percent to $17,314,000.
Phosphagenics said that sales of phosphorylated vitamin E derivatives, by partner Ashland for use in cosmetics, fell 51.0 percent from $1,669,000 in the previous year to $818,000 for the 12 months to December 31, 2016, but the company recorded a 105.2 percent increase in tocopheryl phosphate mixture royalties and licence fees to $636,000.
The company said that diluted loss per share fell 11.6 percent to 1.37 cents at December 31, 2016, with net tangible assets per share down 22.7 percent to 1.02 cents and it had $6,092,000 in cash and cash equivalents at December 31, 2016, compared to $12,395,000 at December 31, 2015.
Phosphagenics fell 0.3 cents or 14.3 percent to 1.8 cents with 2.3 million shares traded.

## ADHERIUM

Adherium says that revenue for the six months to December 31, 2016, was $1,386,000 compared to $1,602,000 for the nine months to December 31, 2015.
Adherium said that the net loss after tax for the six months was up 25.2 percent to $4,808,000 compared to the previous nine month period.
The company said that the sales were primarily through Astrazeneca pilot deployments in Europe, an Australian commercial pilot program, a US chronic obstructive pulmonary disease study and milestones from the New Zealand Medical Research Institute.
The company said that diluted loss per share was 2.9 cents at December 31, 2016, with net tangible assets per share of 17.6 cents.
Adherium said it had cash and cash equivalents of $29,523,000 at December 31, 2016, compared to $27,211,000 at June 30, 2016.
Adherium was unchanged at 19 cents.

## GI DYNAMICS

GI Dynamics says that revenue for the year to December 31, 2016, fell 58.6 percent to $US545,000 ($A708,880) with net loss after tax down 62.7 percent to $US13,116,000 ($A17,059,940).
GI Dynamics said that the decrease in sales across all markets “was a result of a decrease in sales across most geographies”.
The company said that “following the stopping of the Endo trial in the third quarter of 2015 … we decided to focus sales activity on a limited number of countries while disengaging from others” (BD: Jul 30, 2015; Mar 15, 2016).
GI Dynamics said that the reduced loss related to reduced costs of the closed trial, decreased costs of revenue and a decrease in inventory obsolescence.
The company said that net tangible assets per Chess depositary interests (CDIs) fell 75.0 percent to 0.01 Australian cents, with diluted loss per common share down 63.1 percent to $US1.37.
GI Dynamics said that it had cash and cash equivalents of $US8,293,000 at December 31, 2016 compared to $US19,590,000 at December 31, 2015.
GI Dynamics fell 0.6 cents or 12.2 percent to 4.3 cents with two million shares traded.

## ADMEDUS

Admedus says that with regional partner Genpharm it has received approval for its Cardiocel bovine cardiac patch in Saudi Arabia.
Admedus said the approval of the bio-implant for repairing heart defects would increase sales in the Middle East and North Africa region.
Admedus executive chairman Wayne Paterson said that the Saudi approval was “the most significant approval for Admedus and our partners Genpharm in this key strategic region”.
The company said that Saudi Arabia was one of the largest and fastest growing healthcare markets in the Middle East, with a population of more than 32 million people and expected healthcare expenditure rising to $27 billion by 2020.
Admedus said that cardiovascular disease was the main cause of mortality in Saudi Arabia.
Admedus was up three cents or 9.5 percent to 34.5 cents.

## INNATE IMMUNOTHERAPEUTICS

Innate says its phase IIb trial of MIS416 for secondary progressive multiple sclerosis is on schedule to be completed by May and report results by September, 2017.
Innate said the on-schedule 93-patient trial was a double-blinded, randomized, placebo-controlled study into the safety and efficacy of MIS416 once weekly over 12 months.
The company said the last 16 patients would complete the study in the next eight weeks with the last patient visit expected on April 19 and with no safety-related concerns to date.
Innate said that the independent data safety monitoring board had met three times and expressed no concerns regarding the conduct or safety outcomes of the trial.
The company said it had "a high level of interest from the majority of patients who have already completed the trial and who want post-study access to MIS416" and it was working with patients' doctors to ensure access could be arranged.
Innate chief executive officer Simon Wilkinson said that the participants in the study had a wide range of multiple sclerosis-related debilitating symptoms.
"We deeply appreciate the commitment and fortitude with which so many of them have adhered to the requirements of what is an intensive course of treatment and tests over a 52 week period," Mr Wilkinson said.
Innate was up 7.5 cents or 12.7 percent to 66.5 cents with 1.4 million shares traded.

## MMJ PHYTOTECH

MMJ says its Australian distributor HL Pharma Pty Ltd has applied to the Federal Department of Health for a medicinal cannabis import licence.
MMJ said that on receipt of a licence and permit, Swiss subsidiary, Satipharm AG would export its cannabidiol capsules to HL Pharma for distribution to approved customers.
MMJ is in the process of selling Satipharm and United Greeneries to Harvest One, which in turn would be a 60 percent MMJ subsidiary (BD: Feb 23, 2017).
MMJ managing-director Andreas Gedeon said the application was "a significant development … as it represents a clear opportunity to position the business as a trusted supplier of high quality medicinal cannabis products in the Australian market".
MMJ fell half a cent or 1.7 percent to 29 cents with two million shares traded.

## MMJ PHYTOTECH

The Macquarie Group says it has sold shares to below the five percent substantial shareholder level in MMJ Phytotech.
Earlier this month the Sydney-based Macquarie Group said it had become substantial in MMJ with 9,652,632 shares (5.04%) (BD: Feb 10, 2017).
The Macquarie substantial shareholder notice provided 15 pages of related companies and said it sold 2,000,000 shares at 35 cents a share on February 22, 2017.

## ACRUX

Allan Gray Australia has further reduced its substantial holding in Acrux, from 10,288,842 shares (6.18%) to below the five percent substantial level.
Allan Gray said that between February 2 and 24, 2017, it sold 3,625,956 shares for $1,066,874 or 29.4 cents a share.
Earlier this month, Allan Gray said it sold 1,782,430 shares for $570,768 or 32.0 cents a share (BD: Feb 2, 2017).
Acrux fell half a cent or 1.7 percent to 28.5 cents.

## ONCOSIL MEDICAL

Oncosil says it has appointed Dr Martin Cross as an independent non-executive director, with immediate effect.

Oncosil said that Dr Cross was a pharmaceutical executive with 30 years' experience in corporate and industry roles "directly influencing healthcare policy and government legislation in Australia".

The company said that from 2013 to 2015, Dr Cross was the chairman of Medicines Australia and from 2010 to 2013 Dr Cross was chairman of both the Generics Medicine Industry Association and the Pharmaceutical Industry Council, and at the same time was Alphapharm's managing-director.

Oncosil said that previously Dr Cross was Novartis Australia and New Zealand managing-director and prior to that was the head of marketing and sales.

The company said that Dr Cross held a Bachelor of Science and a Doctorate of Philosophy from the University of Aberdeen.

Oncosil was unchanged at 8.6 cents.

## CYNATA THERAPEUTICS

Cynata says it has appointed director Dr Paul Wotton as chairman replacing founding executive chairman Dr Stewart Washer.

Cynata said that Dr Washer would remain on the board as a non-executive director.

The company said that Dr Wotton had "the skills, focus and proven track record to help steer the Company effectively through this next stage of growth".

Cynata said that Dr Wotton had an "investor network and successful track record of growing and building a range of life sciences and stem cell companies".

The company said that, subject to shareholder approval, Dr Wotton would be granted 2,000,000 options exercisable at $1.50 each expiring two years from the grant and vesting in two tranches of 1,000,000 options each at one year and 18 months from grant.

Cynata fell 3.5 cents or 6.6 percent to 49.5 cents.