# Biotech Daily

Thursday June 23, 2016

*Daily news on ASX-listed biotechnology companies*

*** ASX UP, BIOTECH DOWN: IDT UP 4%; ONCOSIL DOWN 14%**

*** REDHILL RHB-104 POTENTIAL EFFICACY FOR CROHN'S DISEASE**

*** MERCK INC PAYS BIONOMICS $978k LICENCE FEE SHARE**

*** GLOBAL KINETICS, US PARKINSON'S FOUNDATION MOVEMENT TRIAL**

*** BIOXYNE CONTRACTS DATAPHARM FOR PROBIOTICS TRIAL**

*** LIVING CELL BERLIN POSTER MAY HAVE PUSHED PRICE 40%**

*** GI DYNAMICS PRESENTS FINAL ENDOBARRIER TRIAL DATA**

*** 'POWER, WATER SHORTAGES' END ANATARA PIG DIARRHOEA TRIAL**

*** UP TO 11% OF SIMAVITA VOTES OPPOSE 100% DIRECTORS POOL HIKE**

*** VIBURNUM, WYLLIE FUNDS TAKE 13.6% OF UNIVERSAL BIOSENSORS**

*** BPH PLEADS 'INVESTOR RELATIONS SPECIALIST' TO ASX 117% QUERY**

## MARKET REPORT

The Australian stock market rose 0.19 percent on Thursday June 23, 2016 with the ASX200 up 9.8 points to 5,280.7 points. Twelve of the Biotech Daily Top 40 stocks were up, 15 fell, 11 traded unchanged and two were untraded. All three Big Caps were up.

IDT was the best, up one cent or 3.85 percent to 27 cents with 146,719 shares traded.

Admedus, Antisense and Universal Biosensors climbed more than three percent; Factor Therapeutics, Medical Developments, Mesoblast and Prana rose more than two percent; Acrux, Avita and Pharmaxis were up more than one percent; with Cochlear, CSL, Resmed and Sirtex up by less than one percent.

Oncosil led the falls, down two cents or 14.3 percent to 12 cents with 1.96 million shares traded.

Cellmid lost 6.25 percent; Living Cell and Orthocell fell more than four percent; Atcor, Biotron and Reva were down more than three percent; Anteo, Osprey and Polynovo shed two percent or more; Actinogen, Impedimed, Nanosonics and Viralytics were down more than one percent; with Clinuvel down 0.2 percent.

## REDHILL BIOPHARMA

Redhill says a published study supports the potential efficacy of RHB-104 for Crohn's disease associated with Mycobacterium avium subspecies paratuberculosis infection.

In 2010, Redhill acquired Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from the Sydney-based Giaconda and their inventor Prof Tom Borody for $US500,000 plus seven percent of net sales (BD: Aug 17, 2010).

Today, Redhill said that the in-vitro study, entitled 'RHB-104 triple antibiotics combination in culture is bactericidal and should be effective for treatment of Crohn's disease associated with Mycobacterium paratuberculosis' was published in Gut Pathogens and authored by scientists from the University of Central Florida College of Medicine's Burnett School of Biomedical Sciences, with an abstract available at: https://gutpathogens.biomedcentral.com/articles/10.1186/s13099-016-0115-3.

The abstract said that RHB-104 was a drug formula with active ingredients composed of Clarithromycin (63.3 %), clofazimine (6.7 %) and rifabutin (30 %) and concluded that "the data clearly demonstrated that lower concentrations of the triple combination of RHB-104 active ingredients provided synergistic anti-MAP growth activity compared to individual or dual combinations of the drugs".

"Consequently, this is favorable and should lead to tolerable dosage that is desirable for long-term treatment of [Crohn's disease] and Mycobacterium avium complex disease," the abstract said.

Redhill said RHB-104 was in its first phase III trial with 200 patients recruited of 270 planned with interim analysis expected by the end of 2016.

The company said that RHB-104 was a "potentially ground-breaking oral antibiotic combination therapy … currently undergoing a first phase III study for Crohn's disease and a phase IIa study for multiple sclerosis".

Redhill chief executive officer Dror Ben-Asher said the final results from the phase IIa study of RHB-104 for multiple sclerosis were expected by the end of 2016.

Last night on the Nasdaq Redhill was up 34 US cents or 3.3 percent to $US10.72.

## BIONOMICS

Bionomics says it has received $US736,815 ($A977,883) in licencing funds as part of an agreement between Merck Sharp and Dohme and Cancer Research Technologies.

Bionomics said the payment from the Kenilworth, New Jersey-based Merck Inc (Merck Sharp and Dohme outside North America), was part of a licence with the Cancer Research Technologies and the Australian Cooperative Research Centre for Cancer Therapeutics for the development of protein arginine methyltransferase 5 (PRMT5).

The company said that high levels of PRMT5 were found in mantle cell lymphoma, chronic lymphocytic leukaemia, melanoma, lung and breast cancers and were linked to low survival rates and PRMT5 inhibitors had potential in treating non-cancer blood disorders such as sickle cell disease and beta thalassemia by initiating genes involved in the development of blood.

Bionomics said the funds were part of a payment of $US15 million to Cancer Research Technologies, with potential milestones of $US500 million and royalty payments on sales, with payments shared between Cancer Research Technologies, the Wellcome Trust, the CRC and partners including Bionomics.

The company said that Merck Sharp and Dohme was responsible for research and development, clinical development, regulatory approvals and the commercialization of products.

Bionomics was unchanged at 29.5 cents.

GLOBAL KINETICS CORP

Global Kinetics says that with the US National Parkinson Foundation it will study continuous measurement of movement in patients with Parkinson's disease.

The Melbourne-based Global Kinetics said that the Miami, Florida-based National Parkinson Foundation would use its Parkinson's Kinetigraph movement recording system to monitor more than 400 Parkinson's disease patients.

Global Kinetics said that its "Parkinson's Kinetigraph mobile health technology for the management of patients with Parkinson's disease and other movement disorders … provides a precise, objective assessment of changes in mobility in patients with diseases and conditions that affect motor skills".

The company said that the wrist-worn device automatically recorded motion data over a period of six days and doctors could download detailed information about the patient's symptoms within minutes, identifying changes and trends that could be important in the diagnosis and treatment of Parkinson's disease.

Global Kinetics said that the device could alert patients when it was time to take medication as prescribed and the patient could acknowledge medication using the device.

The company said that the multi-centre, randomized, controlled trial of more than 400 patients would be conducted as part of the Foundations' Parkinson's Outcomes Project Registry Study which began in 2009.

Global Kinetics said the study was a collaboration with more than 20 movement disorder specialist centres and was the largest clinical study of Parkinson's disease with nearly 9,000 patients enrolled across four countries.

National Parkinson Foundation chief mission officer Dr Peter Schmidt said the Parkinson's Outcomes Project goal was "to identify clinical practices that make a difference in patient outcomes".

"The hope is that this new [Kinetigraph] study will show how we can use technology to provide information to guide better and more effective clinical decisions, helping more people with Parkinson's to achieve the best outcomes they can, and that we will be able to translate this into other care settings," Dr Schmidt said.

Global Kinetics co-founder and chief scientific officer Prof Malcolm Horne said that "one of the great challenges in clinical care of people living with Parkinson's disease is the subjective nature of symptom observation, which can lead to wide variability in use of medicines and in treatment protocols".

"The [Parkinson's Kinetigraph] provides continuous, precise, and accurate assessments of changes in mobility in patients with Parkinson's disease, which can play an important role in helping make informed treatment decisions, this allows clinicians to provide optimum treatment and ultimately leads to better outcomes for people with Parkinson's," Prof Horne said.

Global Kinetics said that data from the Parkinson's Outcomes Project showed wide variability in the use of different medicines and treatment plans in Parkinson's disease and in planning for patient care, physicians typically rely on clinical evaluation, a patient's self-reporting of symptoms and response to medication to guide therapy, potentially increasing the risk of inconsistent and diverse outcomes.

"Some Parkinson's patients are thriving, while others are not," Dr Schmidt said.

"Our goal is to determine what makes that difference," Dr Schmidt said.

Global Kinetics said that its Parkinson's Kinetigraph (PKG) was registered with the Australian Register of Therapeutic Goods, had Conformité Européenne (CE) mark and was cleared by the US Food and Drug Administration.

Global Kinetics is a private company.

## BIOXYNE, DATAPHARM AUSTRALIA

Bioxyne says that Datapharm Australia will conduct a clinical trial to support its Australian launch and marketing of Progastrim and Protract probiotics.

Bioxyne said that the randomized, placebo-controlled trial was expected to begin in August 2016 and would "examine the effect of its human-isolated probiotic strain of bacteria to influence the composition of the gut microbiome in healthy adult human volunteers and … examine what gastro-intestinal health benefits are associated with daily consumption of the strain in the form of freeze-dried powder in capsules".

The company said the strain being tested was Lactobacillus fermentum VRI-003, or PCC, which had been sold as a dietary supplement in capsule and powder form for more than 10 years with no reported adverse effects.

Bioxyne said that the effect of PCC on the composition of the gut microbiome would be analysed using kits from Melbourne-based Smartdna Pty Ltd, which would use nucleic acid analysis to identify the thousands of species in the gut and each volunteer's microbiome would be analysed before, during and at the end of the 6 month trial.

Bioxyne executive director Dr Peter French designed the trial and said it was the first time a probiotic would be tested for its long term effect in healthy humans.

"PCC has been demonstrated in previous trials to have beneficial effects on boosting the immune system of elite male athletes and infants, as well as boosting the immune response to the 'flu vaccine," Dr French said. "Scientific studies have previously shown that PCC exerts its potent effect on the immune system via the gastrointestinal tract."

"This study is designed to further confirm that mechanism," Dr French said.

Bioxyne said that data from the study would be used to promote the gastrointestinal benefits of Progastrim and a second trial of PCC's ability to reduce the symptoms of colds and influenza in healthy adults was being planned for the next Australian winter and would be designed to leverage the mechanistic data from the current trial and be used by the company's distributors to promote PCC's immune benefits in Europe.

Bioxyne was untraded at 2.4 cents.

## LIVING CELL TECHNOLOGIES

Living Cell says that principal investigator Dr Barry Snow will present more than 81 week data from its four patient pilot trial of NTCell for Parkinson's disease.

Yesterday, Living Cell told the ASX that it was not aware of any information it has not announced which, if known, could explain recent trading in its securities, but had previously announced that the data would be presented in Berlin later today.

The ASX said the company's share price had increased by 40 percent from 5.5 cents or June 14 to 7.7 cents on June 22, 2016 and noted and increase in trading volume.

Living Cell said that Dr Snow's poster presentation, entitled 'Safety and clinical effects of NTCell [immunoprotected (alginate-encapsulated) porcine choroid plexus cells for xenotransplantation] in patients with Parkinson's disease (PD): 81 to 130 weeks follow-up' would take place at 12pm Berlin-time today (8pm AEST).

Dr Snow said the data "shows a striking and significant improvement in all measurements of Parkinson's disease in the four patients [and] everything we measured has improved".

Living Cell chief executive officer Dr Ken Taylor said the results were consistent with what was found in pre-clinical studies.

"Moreover microarray analyses identified that several nerve growth factors and nerve protective agents are released from NTCell and this may explain the improvement observed in all of the measurements of Parkinson's disease," Dr Taylor said.

Living Cell fell 0.3 cents or 4.05 percent to 7.1 cents with 1.2 million shares traded.

## GI DYNAMICS

GI Dynamics says it has presented its final results from its halted Endo trial of the Endobarrier duodenum insert for obesity and type 2 diabetes.

GI Dynamics said that principal investigator Dr Lee Kaplan presented the results at the American Diabetes Association meeting in New Orleans, June 10 to 14, 2016.

The company said that the trial "demonstrated clinically meaningful improvements in haemoglobin A1c (HbA1c) levels and weight reduction compared with the sham-treated group" in the 325 patients of the planned 500 subjects.

GI Dynamics said that overall safety was positive except for the higher than expected rate of hepatic abscess, which led to the halt of the trial (BD: Jul 30, 31, 2015).

The company said that no adverse events led to long-term sequelae, or follow-on illness caused by the bacterial liver infections, or mortality.

In March, GI Dynamics said the pivotal trial failed to meet its primary safety and efficacy endpoints and the smaller final sample size provided "less statistical power for analyses than originally planned … [but] the pre-specified analysis methods were used to obtain the results (BD: Mar 15, 2016).

GI Dynamics said in March that the trial showed efficacy for type 2 diabetes with an average reduction of haemoglobin A1c (HbA1c) from baseline to 12 months of 0.71 percent greater with the device than with sham intervention, but the effectiveness did not meet the protocol-specified primary efficacy endpoint, a statistical test to demonstrate a greater than 96.5 percent probability that the change in HbA1c was at least 0.4 percent greater with Endobarrier than with sham control.

GI Dynamics said that the pre-specified probability criterion was 96.5 percent, compared with the result of 92.8 percent.

Dr Kaplan said the study "demonstrates the clinically significant efficacy of Endobarrier therapy for the treatment of type 2 diabetes in patients with obesity".

"While the issue of hepatic abscess needs to be addressed further, this demonstration of benefit underscores the promise of this endo-luminal device," Dr Kaplan said.

GI Dynamics chief executive officer Scott Schorer said the company working to address safety issues and was re-engaging with the FDA for a revised US clinical trial.

GI Dynamics fell 0.4 cents or 14.3 percent to 2.4 cents.

## ANATARA LIFESCIENCES

Anatara says that power and water shortages have caused the termination of its third efficacy study of its pineapple stem-based Detach for diarrhoea control in piglets.

Anatara said that unusual, extreme conditions including power and water shortages at the trial site necessitated the removal of 22 percent of sows and 25 percent of piglets from the study, with limited ability to enrol further pigs.

Anatara said the termination did not affect its ability to submit its dossier required for the Australian Pesticides and Veterinary Medicines Authority's product registration process as planned by October 2016.

The company said that the objective of the third study was to expand the dosing instructions for the final registration label, but the original, single dose regime which was effective in earlier trials would be sufficient for the dossier.

Anatara chairman Dr Mel Bridges said the company "still expects approval for Detach and product launch in Australia in 2017".

The company said that no adverse effects had been reported to date in any of the treatment groups, even at multiple administration of the highest dose rate.

Anatara was up three cents or 2.3 percent to $1.35.

## SIMAVITA

Simavita shareholders have passed all extraordinary general meeting resolutions but with some opposition to the 100 percent increase in the directors remuneration pool.
Simavita said that 5,840,046 votes (10.6%) opposed the increase from $350,000 a year to $700,000 a year with 49,405,237 votes (89.4%) in favor.
All other resolutions were passed by significantly wider margins.
Simavita's most recent Appendix 3B new issue announcement said the company had 104,136,900 shares on issue, meaning the votes against the directors remuneration increase amounted to 5.6 percent of all shares on issue, not sufficient to call extraordinary general meetings.
Simavita was up 0.1 cents or 2.4 percent to 4.2 cents.

## UNIVERSAL BIOSENSORS

Viburnum Funds says it has increased its holding in Universal Biosensors from 20,974,590 Chess depositary interests (11.94%) to 23,852,665 CDIs (13.58%).
The Perth, Western Australia-based Viburnum notice said that between April 21 and June 23, 2016 the funds acquired 2,878,075 shares for $790,880 or 27.5 cents a share
Universal Biosensors was up one cent or 3.6 percent to 29 cents.

## BPH ENERGY

BPH has told the ASX that engaging an investor relations specialist and publishing a research document may have led to a share price jump.
The ASX said the company's share price climbed 116.7 percent from 0.6 cents on June 22 to 1.3 cents on June 23, 2016 and noted an increase in trading volumes.
BPH said it had "recently engaged an investor relations specialist to handle the company's digital investor strategy to increase investor awareness … [and] as part of this campaign, a research document collating previously released information on the company's investments was sent out today to a large number of potential new investors, possibly generating interest in the stock".
BPH has investments in Cortical Dynamics and Molecular Diagnostics.
BPH closed up 0.6 cents or 100 percent at 1.2 cents with 13.6 million shares traded.