



# Biotech Daily

Friday March 4, 2016

*Daily news on ASX-listed biotechnology companies*

- \* **ASX UP, BIOTECH EVEN: POLYNOVO UP 10%, COMPUMEDICS DOWN 9%**
- \* **ADMEDUS CLAIMS PRELIMINARY HSV-2 VACCINE SAFETY, EFFICACY**
- \* **CHINA APPROVES CLINICAL GENOMICS BOWEL CANCER TEST**
- \* **STARPHARMA SIGNS ASPEN FOR VIVAGEL BV FOR AUSTRALIA, NZ**
- \* **COMPUMEDICS 'DOES NOT KNOW' AFR CHINA BRIBE COMPANY**
- \* **TBG (PROGEN) SELLS PHARMASYNTH TO LUINA FOR \$2.2m**
- \* **WEHI: 'CANCERS DEPENDENT ON MCL-1'**
- \* **PROBIOTEC SIGNS NEW CONTRACTS WORTH \$10m A YEAR**
- \* **MGC, SIPNOSE COLLABORATE FOR INTRA-NASAL CANNABINOID**
- \* **BPH RE-APPOINTS GREGORY GILBERT DIRECTOR**
- \* **KENTGROVE TAKES 19.9% OF ALCHEMIA**
- \* **ORTHOCELL APPOINTS PROF ROCKY TUAN TO ADVISORY BOARD**

## MARKET REPORT

The Australian stock market was up 0.18 percent on Friday March 4, 2016 with the ASX200 up 8.9 points to 5,090.0 points. Fourteen of the Biotech Daily Top 40 stocks were up, 15 fell, nine traded unchanged and two were untraded.

Polynovo was the best on no news, up 2.5 cents or 9.6 percent to 28.5 cents with 556,136 shares traded, followed by Admedus up 9.5 percent to 46 cents with 2.1 million shares traded. Oncosil climbed 6.7 percent; Nanosonics, Neuren, Osprey and Psivida rose four percent or more; Atcor was up 3.1 percent; Impedimed and Universal Biosensors were up more than two percent; with Prana, Pro Medicus, Starpharma and Viralytics up more than one percent.

Compumedics led the falls, down 3.5 cents or 8.75 percent to 36.5 cents with 141,678 shares traded, followed by Actinogen down 8.3 percent to 5.5 cents with 689,292 shares traded. Benitec fell 7.7 percent; Anteo lost 6.6 percent; Sirtex fell 4.1 percent; Bionomics, Biotron, Mesoblast and Pharmaxis lost more than three percent; Avita and Uscom shed two percent or more; with Acrux, CSL, Ellex, and Living Cell down more than one percent.

## ADMEDUS

Admedus says its COR-1 herpes simplex virus-2 vaccine has shown safety, a 90 percent decrease in lesions and a reduction of days HSV-2 was detected in patients.

Admedus chief operating officer Dr Julian Chick told Biotech Daily that the interim data from 20 patients in the on-going, 44-patient, double-blinded, randomized, placebo-controlled phase II trial was blinded, so it was unknown how many of the 20 patients received the herpes simplex virus-2 (HSV-2) vaccine and how many received placebo. "This is blinded data, but we are very excited that the trial is going in the right direction," Dr Chick said.

Coridon (now Admedus Vaccines) founder Prof Ian Frazer said that "the initial data appears encouraging and we look forward to additional data from this study being released later this year".

In a media release, Admedus said the scheduled analysis of the first 20 patients to receive at least three vaccinations showed no safety issues and a decrease in viral lesions, or outbreaks, with a drop of more than 90 percent in the monthly rate compared to baseline. The company said that the average number of days HSV-2 was detected in patients was reduced compared to baseline.

Admedus said that the 44 patients were randomized with three active vaccine recipients to one placebo patient and divided into two treatment groups of 22 patients with group 1 receiving inoculations into their left and right arms, with group 2 receiving the double inoculation into one arm.

The company said that the primary endpoint of the study was safety with secondary and investigative endpoints including virological and immunological assessments such as occurrences of outbreaks, viral shedding, viral load, T-cell and antibody counts and safety. Admedus said that post-vaccination and booster virological assessments occurred over 45 days beginning seven days after the third administration of the booster administration and compared to the baseline virological assessments of each patient for a period of 45 days prior to any vaccination.

Admedus chief executive officer Lee Rodne said the decrease in the rate of outbreaks compared to baseline, following administration of the booster and the reduction in the number of days the virus was detected was "very important for this interim review".

"In addition, no safety issues were noted, which is the primary endpoint of the phase II trial," Mr Rodne said.

Mr Rodne said that the next scheduled analysis would be un-blinded and more extensive and was expected by October 2016.

The company said that the data came from the first 20 patients to have received three vaccinations of which 14 had received the booster and the analysis was conducted in a blinded, pooled fashion.

Admedus said that patients were assessed for monthly viral outbreaks and percentage of days where HSV-2 was detected in swabs taken from the patients relative to analogous pre-vaccination measurements as a baseline.

The company said that to date, six patients had withdrawn from the trial for reasons unrelated to vaccine safety, some of whom received their vaccination.

Admedus said it expected all study groups to have completed their dosing, including the booster by the end of 2016 and full trial analysis data to be available by July 2017.

The company said that 417 million people in the 15 years to 49 years age group were living with HSV-2 and a successful HSV-2 vaccine could potentially address a market worth more than \$US6 billion.

Admedus climbed as much as 14 cents or 33.3 percent to 56 cents before closing up four cents or 9.5 percent at 46 cents with 2.1 million shares traded.

## CLINICAL GENOMICS

Clinical Genomics says the China Food and Drug Administration has approved its Insure faecal immune-chemical test (FIT) bowel cancer test.

Clinical Genomics said that the approval was through its China distributor the Beijing-based Biochain Group.

The company said that Insure FIT was developed in Australia and was marketed and sold globally, including the US, with more than 10 million people screened since 1999.

Clinical Genomics Asia-Pacific vice-president Warren Bingham said the company was “delighted with CFDA approval as this represents another international vote of confidence in the company’s cancer testing”.

“Screening for colorectal cancer is a major public health priority for countries around the world,” Mr Bingham said.

“Screening with faecal immunochemical tests is a guideline-endorsed option being adopted worldwide based on clear evidence that it will save lives,” Mr Bingham said.

“Governments are actively seeking affordable, effective and user-friendly cancer screening solutions for their communities,” Mr Bingham said.

“The Insure FIT brush is easy to use and is designed for large screening programs,” Mr Bingham said.

“This test is ideal for large countries such as China with regional and remote communities that may not otherwise have accessible screening options,” Mr Bingham said.

Biochain executive chairman James Wang said the approval came “at an important time when China’s cancer screening program looks set to expand”.

“We are excited to have the opportunity to introduce this effective and user-friendly test in China,” Mr Wang said.

Clinical Genomics is a private company.

## STARPHARMA

Starpharma says Aspen Pharmacare Australia will sell and market Vivagel BV for bacterial vaginosis in Australia and New Zealand.

Starpharma said the terms of the licence and supply agreement with the Durban, South Africa-based Aspen were confidential but it would receive royalties on net sales.

The company said that Aspen was responsible for all marketing, promotion and local distribution of the product to clinicians and pharmacies, with a product launch targeted for this year.

Starpharma said it maintained the manufacturing rights to Vivagel BV and commercialization rights in all other territories of the world, “many of which [were] the subject of active negotiations”.

The company said that Vivagel BV had been approved for marketing in the European Union as a seven day therapy for the topical treatment and relief of bacterial vaginosis including its symptoms and was under review by the Australian Therapeutic Goods Administration through the Australia-EU Mutual Recognition Agreement, with plans underway for a regulatory submission in New Zealand.

Starpharma chief executive officer Dr Jackie Fairley said Aspen was “an ideal sales and marketing partner for Vivagel BV in the Australian and New Zealand markets as they have a proven track record of successfully marketing products in the women’s healthcare segment”.

Dr Fairley said that bacterial vaginosis was “the world’s most common vaginal infection and a significant unmet medical need”.

Starpharma was up 1.25 cents or 1.96 percent to 65 cents.

## COMPUMEDICS

Compumedics says it has no knowledge of, or relationships with, a company accused of bribing Chinese officials.

An article in today's Australian Financial Review said that Compumedics, Melbourne's Box Hill Institute and Brisbane's John Finlay Engineering had been named in court documents, in which four Chinese government officials had been gaoled for corruption.

The Financial Review said that in 2012 Chongqing Aoyuan Medical Equipment Company paid hospital director Zhu Benya a bribe of RMB20,000 (\$A4,217) for approving the purchase of a Compumedics device and Mr Zhu was sentenced to five years gaol.

The Financial Review said that Compumedics didn't know the company that allegedly paid the bribe and wasn't aware of the court case.

The Financial Review reported that the Box Hill Institute had never authorized the payment of bribes and was "greatly disappointed to find out that an international agent purportedly working on our behalf has been involved" in a corruption case, with the University of Southern Queensland and Melbourne Polytechnic named in another trial.

The Financial Review said that one of John Finlay Engineering's staff members was directly involved in a corruption case, according to the court files.

In a media announcement to the ASX, Compumedics said it had relationships with a number of distributors in China, all of whom used sub-distributors.

"Compumedics is not connected with the company referred to in the AFR article," the company said. "The company is not known to Compumedics, nor authorized in any way by Compumedics."

"Compumedics has no knowledge or involvement in the alleged issue," it said.

"Naturally we will undertake our own investigation and review our own policies in order to determine if there is anything further we can do, from our own corporate governance perspective, to avoid issues of this nature arising in the future," the company said.

Compumedics said it had been in business "for almost 30 years, the last 16 of which have been as a public company listed on the Australian Stock Exchange and has an exemplary record when it comes to corporate governance and regulatory compliance, both in Australia and the international countries [in which] it does business".

Compumedics fell 3.5 cents or 8.75 percent to 36.5 cents.

## TBG DIAGNOSTICS (FORMERLY PROGEN PHARMACEUTICALS)

TBG Diagnostics says it will sell its wholly-owned contract manufacturing biopharmaceutical company Pharmasynth to Luina Biotechnology for \$2,200,000.

TBG executive chairman Jitto Arulampalam told Biotech Daily that said that Luina was a consortium of Pharmasynth management and staff and the company would continue from its Brisbane premises.

TBG said that the sale followed a strategic review begun in May 2015 and was one of the final steps as it transformed into an in-vitro diagnostics company following the acquisition of TBG from Medigen and relisting on the ASX (BD: May 1, Dec 14, 2015).

The company said that Pharmasynth chief executive officer Les Tillack would jointly hold about 20 percent of the equity in Luina.

TBG said that the payment would be in three instalments of \$100,000 upfront on the completion date, \$1,000,000 in 24 months and \$1,100,000 in 48 months and the parties would enter into security interest agreements over various assets.

The company said that Pharmasynth had "presented its challenges ... over the years" with a loss of \$271,472 to December 31, 2015 and revenues down 60 percent.

TBG was unchanged at 24 cents.

## THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says its researchers have uncovered a protein that is key to the development of blood cancers caused by a common genetic error.

The Institute said the discovery was “a missing piece in the puzzle” of understanding how high levels of the protein Myc drove cancer development and could lead to strategies for early treatment or prevention of these cancers.

WEHI said that 70 percent of human cancers had abnormally high levels of Myc, which forced cells into unusually rapid growth.

The Institute that Dr Stephanie Grabow, Dr Brandon Aubrey, Prof Andreas Strasser and colleagues discovered that blood cancers driven by Myc could be prevented by lowering the levels of another protein, called MCL-1.

The Institute said that the article, entitled ‘Loss of a Single Mcl-1 Allele Inhibits MYC-Driven Lymphomagenesis by Sensitizing Pro-B Cells to Apoptosis’ was published in the journal Cell Reports and an abstract was available at:

[http://www.cell.com/cell-reports/fulltext/S2211-1247\(16\)30142-5](http://www.cell.com/cell-reports/fulltext/S2211-1247(16)30142-5)

Dr Grabow said the developing cancer cells were dependent on MCL-1, a protein that kept stressed cells alive by preventing programmed cell death, or apoptosis.

“No one had realised just how vulnerable cells undergoing cancerous changes are to a relatively minor reduction in the levels of MCL-1,” Dr Grabow said .

“We found that MCL-1 is critical for keeping developing cancer cells alive through the stressful events that cause the transformation of a healthy cell into a cancerous cell,” Dr Grabow said. This result is particularly exciting because MCL-1 inhibitors are already in development as anti-cancer drugs.”

“Our colleagues had previously discovered that reducing the activity of MCL-1 is a promising strategy to treat malignant Myc-driven cancers,” Dr Grabow said.

“We have now shown that the same approach might be able to prevent those cancers from forming in the first place,” Dr Grabow said.

Royal Melbourne Hospital clinical haematologist Dr Aubrey said the research could inform future strategies to prevent cancer.

“Early treatment or even cancer prevention are likely to be a more effective way to fight cancer than treating an established cancer after it has already formed and made a person sick,” Dr Aubrey said. “Our research has suggested that dependency on MCL-1 could be a key vulnerability of many developing cancers.”

“In the future MCL-1 inhibitors might have potential benefit for treating the very early stages of Myc-driven cancers, or we may even be able use these agents to prevent people from getting cancer in the first place,” Dr Aubrey said.

## PROBIOTEC

Probiotec says agreements with existing and new contract manufacturing customers for additional products are expected to generate about \$10 million a year.

Probiotec said that the new business was expected to come on-line progressively over the 2016-'2017 financial year, predominantly in the six months to June 30, 2017.

The company said it continued “to enjoy strong demand from its existing contract manufacturing customers and is pursuing additional opportunities to achieve further growth in this key pillar of the business”.

Last week, Probiotec said its revenue for the six months to December 31, 2015 was up 2.4 percent to \$30,154,367 taking the previous net loss after tax of \$26,099,715 to a profit of \$2,094,215 (BD: Feb 25, 2016).

Probiotec was up two cents or 4.4 percent to 47 cents.



### MEDICAL GRADE CANNABIS PHARMACEUTICALS

MGC Pharmaceuticals says it will collaborate with Israel's Sipnose to combine its cannabinoids with Sipnose's intra-nasal drug delivery system.

MGC company secretary Rachel Kerr told Biotech Daily that on February 23, 2016 MGC completed its backdoor listing into Perth-based gold-mining company Erin Resources.

In a media release to the ASX, MGC said its cannabinoid (CBD) compounds were intended to treat patients with central nervous system disorders, initially focussing on the symptoms of epilepsy, a disease impacting 65 million people worldwide

The company said that with Sipnose it would begin a medical research and development program at Israel's Hadassah Medical Centre.

In December, MGC said it was "on-target to execute the first sales of its initial range of CBD-based cosmetic products in January 2016" and it had completed phase I testing on its CBD skin care formula with its Ananda joint venture partner Natura Laboratories and Dr M Burstein Ltd, which "demonstrated excellent results on patients with psoriasis and was proven to be an effective relief for the skin from dryness, inflammation and flaking".

The company said that phase II trials and programs were progressing well and the final phase III testing programs were on-track to begin by April 2016 and on completion, it would have its first European Union compliant over-the-counter CBD dermatological product available for sale, which was on schedule for sales by July 2016.

MGC fell 0.1 cents or 3.2 percent to three cents with 12.6 million shares traded.

### BPH ENERGY

BPH, which has investments in Cortical Dynamics and Molecular Discovery, says it has re-appointed Gregory Gilbert as an independent non-executive director.

Mr Gilbert resigned from BPH in 2013 "to take up other business commitments", namely the appointment as a science adviser to the then Federal Minister for Industry and Science Ian Macfarlane (BD: Dec 13, 2013).

BPH said Mr Gilbert had experience in the health and aged care sector as well as in merchant banking and held positions in global strategy and finance at the National Australia Bank and was an executive at Capel Court Investment Bank and CIBC Australia.

BPH said Mr Gilbert was a former Australian Army lieutenant-colonel with experience in strategic planning, financial management, change and project management, merchant banking and corporate advisory experience in mergers, acquisitions and valuations.

The company said that Mr Gilbert held a Bachelor of Arts from the University of Queensland, a Diploma of Applied Science from the Royal Military College Duntroon, a Masters in Science from Cranfield University UK, a Masters in Health Administration from La Trobe University and a Masters of Business Administration from Deakin University.

BPH was untraded at 0.7 cents.

### ALCHEMIA

The Melbourne-based Kentgrove Capital says it has become a substantial shareholders in Alchemia with 64,619,996 shares or 19.9 percent of the company.

In a substantial shareholder notice from director David Lamm, Kentgrove said that the registered holders of the shares were TTOR Pty Ltd, Parkbay Capital and Adam Saunders and the shares were bought on February 29, 2016 for \$516,960 or 0.8 cents a share.

Last year Genetic Technologies said it had a \$24 million standby equity facility with Kentgrove Capital Growth Fund (BD: Jan 22, 2015).

Alchemia was unchanged at 0.8 cents.

## ORTHOCELL

Orthocell says it has appointed Prof Rocky Tuan to its medical and scientific advisory board to advise on clinical research and product development.

Orthocell said Prof Tuan was a widely published and respected expert in regenerative medicine and stem cells and currently the University of Pittsburgh's director of the Centre for Cellular and Molecular Engineering in the Department of Orthopaedic Surgery and director of the Centre for Military Medicine Research.

The company said that Prof Tuan held a secondary appointment as a professor within the Department of Bioengineering.

Orthocell was unchanged at 39 cents.