

Biotech Daily



Monday November 28, 2016

Daily news on ASX-listed biotechnology companies

- * **ASX DOWN, BIOTECH UP: ADMEDUS UP 8%, AIRXPANDERS DOWN 7%**
- * **SIRTEX STC314 FOR SEPSIS LEADS 4 NEW R&D PROGRAMS**
- * **HUNGARY \$3m FOR USCOM LUNG CANCER TEST CONSORTIUM**
- * **STARPHARMA APPOINTS KOUSHAN FOR VIVAGEL CONDOMS IN IRAN**
- * **ONCOSIL NAMES HOSPITALS FOR PANCREATIC CANCER TRIAL**
- * **MIZUNO USES DORSAVI'S VIMOVE TO SELECT RUNNING SHOES**
- * **P&G LICENCES OBJ WAVE II MAGNETIC COSMETICS APPLICATOR**
- * **CANADA PERMITS MMJ 1kg MARIJUANA SEEDS, RECREATIONAL USE**
- * **MEMPHASYS REMUNERATION FACES 17.6% OPPOSITION**
- * **PROBIOTEC BETS ON CHAIR GEOFFREY PEARCE FOR AGM SPILL**
- * **JASON PETERSON, CELTIC TAKE 12% OF ZELDA**
- **CHAIR HARRY KARELIS, GEMELLI 7%, AUNT ZELDA, MARA GORDON 12%**
- * **LIVING CELL TAKES CAPITAL RAISING HALT TO SUSPENSION**
- * **PHYLOGICA LOSES DIRECTOR, FORMER CHAIRMAN DR DOUG WILSON**

MARKET REPORT

The Australian stock market was fell 0.79 percent on Monday November 28, 2016 with the ASX200 down 43.4 points to 5,464.4 points. Sixteen of the Biotech Daily Top 40 stocks were up, 10 fell, eight traded unchanged and six were untraded. All three Big Caps fell.

Admedus was the best, up three cents or 8.3 percent to 39 cents with 869,002 shares traded. Impedimed climbed 6.4 percent; Mesoblast rose 4.1 percent; Pharmaxis improved 3.8 percent; Opthea, Orthocell, Prima and Pro Medicus were up more than two percent; Bionomics, Factor Therapeutics, Universal Biosensors and Viralytics were up more than one percent; with Clinuvel, Medical Developments, Sirtex and Starpharma up less than one percent.

Airxpanders led the falls, down nine cents or 7.2 percent to \$1.16 with 115,941 shares traded. Compumedics lost 5.8 percent; Benitec and Neuren fell more than four percent; Cellmid was down 3.3 percent; Atcor shed 2.9 percent; Acrux was down 1.5 percent; with Cochlear, CSL, Ellex, Nanosonics, Psivida and Resmed down by less than one percent.

SIRTEX MEDICAL

Sirtex has described three previously mentioned non-SIR-Spheres research and development programs, along with unveiling STC314 targeting histones for sepsis. In a webcast, Sirtex chief executive officer Gilman Wong said the company hoped to develop its radio-protector, carbon-cage nanoparticles and polymer coated nanoparticles programs to a point where they could be out-licensed.

Mr Wong said that Sirtex was investigating STC314 which targeted extra-cellular histones released from dead and dying cells and was implicated in sepsis.

Sirtex head of research and development Dr Steve Jones told the webcast that severe sepsis was a life-threatening inflammatory response to infection with 750,000 US cases leading to 215,000 deaths each year and was "the single most expensive condition treated in US hospitals".

Pharmaventures chief executive officer Dr Fintan Walton told the webcast that sepsis treatment cost the US hospitals \$US20 billion a year.

Dr Jones said that extra-cellular histones were validated as major mediators of the hyper-inflammatory response in sepsis and were released from dead and dying cells at the beginning of the cascade of events that led to sepsis.

Dr Jones said that if Sirtex could inhibit extra-cellular histones it hoped to prevent the events that led to sepsis, including the death of endothelial cells lining blood vessels, impaired blood perfusion, coagulation, thrombosis and multiple organ failure.

Dr Jones said that Sirtex was working with the Australian National University in Canberra and Griffith University in New South Wales and its patents extending beyond to 2030.

Dr Jones said that pre-clinical models had shown safety and extended survival and the company hoped to begin its first-in-human phase Ia single ascending dose two-hour infusion trial by July 2017, to be followed by a phase Ib three-day infusion trial.

He said that the phase II and III trials were expected to be much shorter than cancer trials. Sirtex has previously mentioned its radio-protector, carbon-cage nanoparticle and polymer coated nanoparticle programs but without providing detail.

Today, Dr Jones said that the radio-protector program was being developed with Melbourne's Peter MacCallum Cancer Clinic and was hoped to reduce the sensitivity of normal tissue allowing an increased dose of radiation to the tumors.

Dr Jones said the radiation side-effect of oral mucositis in head and neck cancers could interrupt treatment, compromising tumor control, and a small improvement in the dose to toxicity ratio could have significant consequences for treatment outcomes.

Dr Jones said that a lead candidate was expected to be identified in 2017 with human clinical studies beginning in 2018.

Dr Jones said that the carbon cage nanoparticle program was in collaboration with the Australian National University and the nanoparticles of metallic radio-isotopes were encapsulated in graphite carbon, with applications in diagnostic imaging for deep vein thrombosis and pulmonary embolism, as well as image-guided surgery for liver cancer. He said that Sirtex was conducting in-vivo safety, toxicity and efficacy studies and expected to begin human clinical trials in 2018.

Dr Jones said that Sirtex was working with the University of Sydney on its polymer coated iron oxide nanoparticle program which would allow the invisible or stealth-like delivery of a drug payload to a target and could be used for medical imaging and drug delivery, along with enhanced penetration of chemotherapy drugs.

He said that Sirtex was investigating the combination of its polymer-coated nanoparticles with chemotherapy in pre-clinical models of metastatic ovarian cancer, with a proof of concept trial expected by July 2017.

Sirtex was up 22 cents or 0.8 percent to \$28.59 with 188,135 shares traded.

USCOM

Uscom says it is part of a consortium awarded a three-year EUR2.2 million (\$A3.1million) grant to develop an exhaled breath condensate lung cancer test.

Uscom said that the Hungarian National Research, Development and Innovation Office grant was awarded to Uscom Europe, the Hungarian Academy of Sciences Material Sciences Department and Budapest's Semmelweis University Medical School.

The company said that the total value of the project was EUR2.7 million and it would receive EUR300,000 in the first stage of the project.

Uscom said the project was entitled 'Material research and development for the implementation of extracellular vesicular based medical diagnostics' and it would develop a new exhaled breath condensate device, using technology derived from its digital ultrasonic spirometers and respiratory monitoring devices.

The company said that the device would extract condensate from the exhaled breath from which exosomes could be isolated.

Uscom said that the exosomes contained RNA, lipids, proteins and metabolites which reflected the type of cell from which they originated and could be analyzed to identify a wide variety of diseases.

The company said that the application of the exosomes as biomarkers had proven promising for the early detection of lung and other cancers, and cystic fibrosis.

Uscom said that the project would result in it owning intellectual property and a right of first refusal for any other intellectual property developed in the three year project.

Uscom executive chairman Prof Rob Phillips, a co-author of the project, said that "development of efficient methods for early and accurate detection of lung cancer and a wide range of viral, microbial, neoplastic [or cancer] and genetic diseases from a simple breath test may lead to widespread population screening".

"Exosome study is a rapidly growing focus of medical science and this grant from the Hungarian Government is recognition of the quality of science within Uscom and its proven expertise in technology development," Prof Phillips said.

"This research may also generate a new generation of medical devices with potentially life-saving applications and global commercial application and may result in a pipeline of new devices for Uscom, just as we bring our new BP+ and Spirosonic devices to market," Prof Phillips said.

Uscom was untraded at 22.5 cents.

STARPHARMA HOLDINGS

Starpharma says it has a licence and supply agreement with the Tehran-based Koushan Pharmed to sell and market Vivagel condoms in Iran.

Starpharma said that Iran was an attractive retail market for condoms with more than 60 percent of the 75 million people under 30 years of age.

The company said that Koushan was a privately-owned company with a portfolio of pharmaceutical, over-the-counter and medical device products.

Starpharma said it would supply Vivagel condoms and Koushan would be responsible for registering the product through the Iranian Ministry of Health, as well as marketing, promotion and local distribution, but said the commercial terms were confidential.

Koushan managing-director Dr Amir Vali said his company expected to launch the product in 2017.

Starpharma was up half a cent or 0.75 percent to 67.5 cents.

ONCOSIL MEDICAL

Oncosil says the US arm of its 300-patient pivotal pancreatic cancer trial will be conducted at Johns Hopkins Hospital and MD Anderson Cancer Centre.

Oncosil said that Guy's and St Thomas' Hospitals in London and Melbourne's Monash Health had agreed to participate in the study, with investigational review board process underway at the two US centres, central regulatory and governance applications initiated in the UK and ethics submission filed to Monash Health and under review.

Oncosil chief executive officer Daniel Kenny said a further 11 centres in the US, UK and Australia were evaluating the feasibility of participating in the study.

In August, Oncosil said that the US Food and Drug Administration has approved an investigational device exemption application for the multi-centre, randomized, open-label 'Oncopac-1' safety and efficacy trial for patients with locally advanced, unresectable pancreatic adeno-carcinoma (BD: Aug 2, 2016).

Oncosil was unchanged at 10 cents.

DORSAVI

Dorsavi says that sports shoe manufacturer Mizuno Group has used its Dorsavi Vimove in a UK pilot program to better understand and inform shoe selection.

Dorsavi said that the Osaka, Japan-based Mizuno Running Solution used the Vimove Run sensors to wirelessly measure and record movement and the impact of up to nine variables while the customer ran on a treadmill.

According to the Mizuno website, the Running Solution "takes the guesswork out of finding your perfect running shoe" through the wearable sensor to provide an individual data set for each shoe tested and "Vimove converts these readings into hard data, not hunches".

Dorsavi said that the assessment was conducted "in a matter of minutes providing the retail assistant with analyzed results which they could explain to the customer and use to match them with the most appropriate running shoe".

Dorsavi said that Yourphysioplan was its UK distributor and co-founder Andy Curtis said the initial results were "very encouraging ... [and] the running assessment with Vimove Run impacting positively on sales in these stores, but also in engaging customers with personalized information which they value".

Dorsavi chief executive officer Dr Andrew Ronchi said the Mizuno pilot program was "the first retail implementation of our technology and it's great to see the applicability of the detailed movement analysis data we can provide being used in a completely new way".

Dorsavi was untraded at 46 cents.

OBJ

OBJ says that Procter & Gamble has executed the licencing terms for the Wave II magnetic array cosmetics applicator device (BD: Oct 26, 2016).

In October, OBJ said the two companies had collaborated on the Wave II development over the last two years and the term sheet was the second product in the schedule of the master licence agreement (BD; Aug 8, 2016).

The company said that the first licence term sheet, known as Wave I, was initially launched as the SKII Eye Wand product and later as the Olay Eye Wand and was distributed by Procter & Gamble.

OBJ said that the Wave II used its magnetic microarray technology and incorporated new features to further enhance performance and user experience.

OBJ was up 0.1 cents or 1.5 percent to 6.9 cents with 2.05 million shares traded.

MMJ PHYTOTECH

MMJ says Health Canada and the Canadian Food Inspection Agency have approved a permit for subsidiary United Greeneries to import 1kg of cannabis seeds.

MMJ said the seeds would come from an undisclosed European source.

The company said that the permit would allow United Greeneries to begin cultivation activities at the Duncan, British Columbia facility in December.

MMJ said the permit made it one “of a select number of companies operating in the Canadian cannabis market with the capacity to import critical starter material required to grow commercial quantities of cannabis”.

The company said that due to international prohibitions on the transport and importation of cannabis, the availability of legal starter materials was “extremely limited” but it had identified “a solution to solve this industry bottle neck” and would be able to provide Canadian consumers with a broad range of cannabis varieties that were not previously legally available in Canada.

MMJ said that it would expand the Duncan facility from an initial 7,500kg of cannabis by the end of 2018 in the first full year of production to 60,000kg by 2022.

MMJ managing-director Andreas Gedeon said it was “one of very few importation licences to have ever been issued, paving the way for United Greeneries to import an unprecedented range of cannabis genetics”,

“United Greeneries will be able to supply the Canadian market with a variety of cannabis strains that cover the entire spectrum of cannabinoid profiles, including most tastes and flavors the plant has to offer,” Mr Gedeon said.

“We believe this will give us a significant marketing advantage when it comes to catering to specific client demands, as we look to position as a first mover in the Canadian recreational market,” Mr Gedeon said.

“United Greeneries is expected to have the material in its possession within the next two weeks and commence growing operations at the Duncan facility in December, with a view to increasing production [by April] 2017,” Mr Gedeon said.

MMJ was unchanged at 20 cents with 1.75 million shares traded.

MEMPHASYS

Up to 17.6 percent of Memphasys annual general meeting votes opposed the remuneration report with significant opposition to director Dr Robert Gilmour options.

The remuneration report was opposed by 12,828,603 votes (17.60%) and supported by 55,342,587 votes (75.95%) with 4,700,686 votes at the proxy’s discretion.

In October, Memphasys said that shareholders would vote to issue executive chair Alison Coutts 24,000,000 options with 4,000,000 options for former director Dr Robert Gilmour and 3,000,000 options for Platinum Road (BD: Oct 31, 2016).

The company said that 48,061,918 votes (15.22%) opposed the issue of options to Dr Gilmour with 263,079,105 votes in favor (83.29%) and 4,709,953 votes at the proxy’s discretion.

Memphasys said that the Platinum Road options resolution was withdrawn prior to the meeting “as the business that it relates to is not completed”.

The company said that all other resolutions were passed easily.

The company’s most recent Appendix 3B said that Memphasys had 569,234,004 shares on issue meaning that the largest opposition vote, to Dr Gilmour’s options, amounted to 8.9 percent of the company’s total shares on issue, sufficient to requisition extraordinary general meetings.

Memphasys was unchanged at 0.4 cents.

PROBIOTEC

Probiotec says it has a number of board changes following discussions ahead of the annual general meeting on November 29, 2016.

In September, Probiotec founder and former executive director Charles Wayne Stringer was a signatory to a call to remove directors Robert Maxwell Johnston and Richard David Kuo (BD: Sep 23, 2016).

Earlier this month Mr Stringer increased his holding from 9,637,690 shares (18.2%) to 12,460,845 shares (23.54%) in an association with the Balwyn North, Melbourne-based Ganter Corp and Rudi Ganter which would cease following the company's annual general meeting (BD: Nov 8, 2016).

Today, Probiotec said that the parties had agreed settlement terms, including the appointment of Geoffrey Ronald Pearce as an independent, non-executive director and chairman.

The company said that Mr Pearce was a Melbourne-based entrepreneur with more than three decades as an import wholesaler and contract manufacturer in the skin, hair, bath and body field and was currently the managing director of the Continental Group and the president of the poker-machine operator Australian Leisure and Hospitality Group-owned Aces Sporting Club.

Probiotec said that directors Mr Johnston, Mr Kuo and Graham Buckeridge had resigned. The company said that if Mr Pearce and Graham Morton were re-elected as directors at the meeting, they would join Wesley Stringer on the board.

Probiotec said that it would appoint a recruitment consultant to undertake a search for an additional independent non-executive director, expected in early 2017.

The company said it would undertake a strategic direction analysis.

Probiotec was up 1.5 cents or three percent to 51.5 cents.

ZELDA THERAPEUTICS

Jason Peterson and associates says they have increased their substantial holding in Zelda from 60,441,855 shares (10.02%) to 80,292,388 shares (12.0%).

The Perth, Western Australia-based Mr Peterson said that the shares were held in the name of the Jason and Lisa Peterson Superannuation Fund, Celtic Capital, CPS Capital Group and Professional Payment Services Pty Ltd.

Mr Peterson said that the shareholding was affected by the one-to-five consolidation and the receipt of consideration shares as well as an in specie distribution from MJ Life Sciences, along with the on-market sale of shares.

Zelda was unchanged at 2.4 cents.

ZELDA THERAPEUTICS

Gemelli Nominees says it has increased its substantial holding in Zelda from 6,666,667 shares (5.53%) to 49,587,680 shares (7.41%).

In a substantial shareholder notice signed by the Perth, Western Australia-based Gemelli's director and Zelda chairman Harry Karelis Gemelli said that the 42,921,013 shares were "issued as part of [the] acquisition of Zelda".

ZELDA THERAPEUTICS

Zelda Director Mara Gordon says she has become a substantial shareholder in Zelda with 79,642,326 shares (11.90%).

The Bodega Bay California-based Ms Gordon is the founder of Aunt Zelda which was the major shareholder in Zelda with about 30 percent, prior to the initial public offer.

LIVING CELL TECHNOLOGIES

Living Cell has requested a voluntary suspension to follow the trading halt requested on November 24, "pending a capital raising through Hunter Capital Advisors" (BD: Nov 24, 2016).

Living Cell last traded at 9.1 cents.

PHYLOGICA

Phylogica says that Dr Doug Wilson resigned as a non-executive director, effective from the annual general meeting on November 25, 2016.

Phylogica said that Dr Wilson became a director in December 2007, an executive director in December 2008, executive chairman in 2009 and non-executive chairman in November 2012 until October 2015, when he became a non-executive director.

Phylogica was unchanged at 1.6 cents.