



Biotech Daily

Monday December 4, 2017

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: ONCOSIL UP 9%; VOLPARA DOWN 8%**
- * **CE MARK FOR BURNET, OMEGA VISITECT P-O-C HIV TEST**
- * **BURNET, OIL SEARCH PARTNER FOR PNG HEALTH**
- * **PROTEOMICS, BUSSELTON COLLABORATE ON LUNG DIAGNOSES**
- * **TBG, XIAMEN HIACANG JOINT VENTURE MEDICAL LAB**
- * **PHOSPHAGENICS: RODAN + FIELDS TPM COSMETICS LICENCE**
- * **PHYLOGICA DROPS PROGRAMS TO FOCUS ON PENETRATING PEPTIDES**
- * **DOETSCH GREYER TO DISTRIBUTE CRESO CANNAQIX10 SUPPLEMENT**
- * **NOXOPHARM: 'COMPASSIONATE USE PATIENT NOX66 RESPONSE'**
- * **MORGAN STANLEY 'RETURNS COLLATERAL' BELOW 5% OF VIRALYTICS**
- * **CORMORANT REDUCES TO 5% IN VIRALYTICS**
- * **RENAISSANCE TAKES 6% OF GENETIC TECHNOLOGIES, 'CODING ERROR'**
- * **ADHERIUM QUIETLY LOSES FOUNDER GARTH SUTHERLAND**
- * **TELEX APPOINTS DR BERNARD LAMBERT HEAD, COO TELEX US**
- * **IMUGENE APPOINTS PETER SCHMID ADVISOR**

MARKET REPORT

The Australian stock market slipped 0.07 percent on Monday December 4, 2017 with the ASX200 down 4.2 points to 5,985.6 points. Fourteen of the Biotech Daily Top 40 stocks were up, 19 fell, five traded unchanged and two were untraded. All three Big Caps fell.

Oncosil was the best, up 1.5 cents or 9.4 percent to 17.5 cents with 2.9 million shares traded. Optiscan and Viralytics climbed more than seven percent; Avita and Polynovo rose more than six percent; Pro Medicus improved 4.1 percent; Admedus and Starpharma were up more than three percent; Benitec and Factor Therapeutics rose more than two percent; with Osprey and Sirtex up by more than one percent.

Volpara led the falls, down five cents or 7.8 percent to 59 cents with 233,287 shares traded. Cyclopharm lost six percent; Clinuvel and Neuren fell more than five percent; Genetic Signatures, Mesoblast and Orthocell were down three percent or more; Compumedics, Impedimed, ITL, Medical Developments, Prana and Reva shed more than two percent; with Ellex, LBT, Nanosonics, Opthea, Resmed and Universal Biosensors down more than one percent.

THE BURNET INSTITUTE

The Burnet Institute says its Visitect CD4 point-of-care HIV test co-developed with the Alva, Scotland based Omega Diagnostics has been granted Conformité Européenne (CE) mark.

The Burnet said that the approval followed performance evaluations in India and the UK and Visitect CD4 was “the world’s first instrument-free and affordable rapid test for determining CD4 threshold in people living with HIV”.

The Institute said that the Visitect CD4 would enable patients in rural locations to access testing more easily and did not require investment in equipment or highly technical scientific staff to operate.

The Burnet said that the test would proceed to further regulatory processes necessary before being implemented in those regions where HIV remains a significant public health challenge.

Burnet deputy director Prof David Anderson said that achieving CE mark was an important step in the roll out of this small, but potentially life-saving diagnostic.

“The Burnet Institute is delighted to witness the commercial release of the Visitect CD4 test by our partners at Omega Diagnostics,” Prof Anderson said.

“Despite the adoption of broader HIV treatment access policies in many countries, the fact remains that many people are first diagnosed with advanced disease and low T-cell counts that require additional interventions above and beyond just anti-retroviral therapies,” Prof Anderson said.

“CD4 testing is critical for identifying the patients for whom these extra efforts are needed, and will remain an important tool in HIV treatment and care for many years,” Prof Anderson said.

THE BURNET INSTITUTE

The Burnet Institute says it has formed a partnership with the Oil Search Foundation “to improve the health of Papua New Guineans”.

The listed mining company Oil Search said it was the founder and principal donor to the Oil Search Foundation, and had assets in Papua New Guinea and Alaska.

A joint media release said that the Foundation would “contribute its knowledge and expertise on health systems strengthening and service delivery, provincial health authorities, health financing, large-scale program implementation, grant management and monitoring and evaluation.

The Burnet Institute said it would contribute technical expertise in addressing tuberculosis, HIV and AIDS, maternal and child health and sexual health.

A Burnet spokesperson told Biotech Daily that the Institute had on-going programs including the ‘Healthy mothers, healthy babies’ program based in Kokopo in East New Britain and was working with Australia’s Department of Foreign Affairs and Trade in a consortium on tuberculosis eradication, especially drug-resistant tuberculosis in Daru.

The media release said that partnership’s first major commitment would be to identify significant donor-funded health activities on which to jointly bid.

Burnet director and chief executive officer Prof Brendan Crabb said the partnership would enhance both parties’ track record of delivering results.

“The most important issue here is that Burnet and OSF have shared values,” Prof Crabb said.

“We share a goal to improve the health and lives of Papua New Guineans and have the opportunity to deliver targeted activities where they’re most needed,” Prof Crabb said.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it will work with the Busselton Population Medical Research Institute to improve diagnosis and treatment of asthma and chronic obstructive pulmonary disease. Proteomics said that the collaboration with Busselton's long-running epidemiological research programs, which began in 1966, would allow its scientists to ask precise questions about the onset of disease.

Proteomics said that COPD included emphysema, airway inflammation and narrowing and was associated with chronic bronchitis, and was commonly misdiagnosed.

Proteomics managing-director Dr Richard Lipscombe said that large patient groups with healthy matched controls were "the key to unlocking new diagnostic tests".

"Working with the Busselton Health Study is tremendous because it gives us access to a unique collection of accumulated data and biological specimens," Dr Lipscombe said.

"This allows us to rule out confounding variables that hide subtle differences, and look for new markers for disease that others may never see," Dr Lipscombe said.

Proteomics said that asthma affected about 2.5 million Australian with an estimated cost of \$27.9 billion in 2015 and in industrialized countries, up to 15 percent of adults have COPD, which was the third most common cause of death in the US.

The company said that tests for asthma and COPD measured lung function using a spirometer measuring the amount of air a patient could exhale and it was difficult to perform in children younger than five years, while chest X-rays and computed tomography scans and responses to treatment could help diagnosis but were not always definitive.

The company said that preliminary results from the asthma and COPD study would be available in six to nine months and if successful a new diagnostic test could be available in two to three years.

Proteomics said it would have the right to commercialize any diagnostic markers found, with the Institute receiving a royalty on use of the test.

Proteomics climbed 4.5 cents or 23.1 percent to 24 cents.

TBG DIAGNOSTICS

TBG says it will form a RMB30 million (\$A6 million) joint venture with Xiamen Haicang Biotechnology Development Co to build and operate a medical laboratory.

TBG said its wholly-owned subsidiary TBG Biotechnology Corp would hold 60 percent of the joint venture, with and the Haicang Government-owned Haitou Group's Xiamen Haicang holding 40 percent.

The company said the laboratory would be at its facility in the Xiamen Biobay, an industrial park home to more than 100 biomedical enterprises in Haicang district.

TBG said that the laboratory would will occupy 1,200 square meters on the third floor of it premises in the Biobay and would "serve the clinical diagnostic needs of hospitals in the Xiamen City as well as Fujian and neighbouring provinces in transplantation, blood and platelets transfusion, cancer and genetic diagnostics" as well as support the companies in the Biobay for their needs in product research and developments.

The company said that the Xiamen Government had given permission for the joint venture to establish the laboratory with the formal licence expected in May 2018 when construction was completes and staff were in place.

TBG chief operating officer Eugene Cheng said that TBG had "taken a step further from product development and manufacturing to providing services to the health sector and especially by building partnership with an esteemed company like Xiamen Haicang".

TBG was unchanged at 8.4 cents.

PHOSPHAGENICS

Phosphagenics says it has a non-exclusive licence agreement with Rodan + Fields for the use of its tocopheryl phosphate mixture (TPM) for cosmetics.

Phosphagenics said that the licence covered the US, Canada, Australia, Japan and South Korea, with the San Francisco, California-based Rodan + Fields skin care company responsible for all development and commercialization.

The company said that it would receive a one-time \$US50,000 (\$A65,777) payment within the next 30 days and Phosphagenics would be the exclusive provider of tocopheryl phosphate mixture, derived from either a natural or synthetic vitamin E source “on commercially attractive terms”.

Phosphagenics chief executive officer Dr Ross Murdoch said that Rodan + Fields spent “some considerable time assessing TPM”.

“We see this relationship as having the potential to drive new products and add great value to both companies,” Dr Murdoch said.

Phosphagenics rose 0.1 cents or 6.7 percent to 1.6 cents with 1.7 million shares traded.

PHYLOGICA

Phylogica says it will de-prioritize all internal product development programs in favor of commercializing its functional penetrating peptide intracellular delivery technology.

Phylogica said that the de-prioritized programs included its iMyc, Stat5 and YB1 programs and its ‘pivot to platform’ presentation at its annual general meeting said the functional penetrating peptide (FPP) program was intended to bring drugs to the right intracellular targets, enhance properties of drugs by improving the therapeutic window and reducing discovery cycle time, improving the drug profile.

The company said the change of direction provided “a defined and shorter path to value creation for shareholders through focusing resources on the FPP delivery technology.

Phylogica said its key objective in 2018 was “to significantly expand the validation of the FPP intracellular delivery technology and its ability to carry a diverse range of cargo types into different tissue and cell types, both in-vitro and in-vivo”.

Phylogica said that demonstrating efficacy of different FPP-cargo conjugates in an animal model ... and the delivery of therapeutically relevant cargo classes ... represent significant milestones on the path towards commercialization of a delivery technology”, with the realization of the milestones of “significant interest” to prospective partners.

Phylogica said it aimed to generate in-vivo efficacy data by July 2018 for an immunotherapy peptide vaccine, antibodies, gene editing technology, anti-microbial peptides, Cre-recombinase and the clustered regularly interspaced short palindromic repeats (CRISPR)/Cas9 genome editing tool.

The company said that successful delivery of the cargoes would demonstrate the ability of the FPP delivery technology to carry a diverse range of cargoes including: proteins, antibodies, enzymes, gene-editing technology, immunotherapy vaccine cargoes and antimicrobial peptides inside the cell.

Phylogica said the cargoes had been selected to provide in-vivo proof-of-concept for the delivery technology and identify areas of high value and interest to prospective partners.

The company said that its FPP-iMyc product was intended to form part of the validation for the FPP platform and as part of the strategic review, it decided that the significant cost and resources to further optimize the drug-like properties of the FPP-iMyc candidates would not be funded internally, but the iMyc program would continue under the National Health and Medical Research Council grant.

Phylogica was up 0.2 cents or 4.9 percent to 4.3 cents with two million shares traded.

CRESO PHARMA

Creso says the Swiss pastille company Doetsch Grether will market and distribute its hemp-based Cannax10 in Switzerland and Liechtenstein as a food supplement. Creso said the agreement “sets the cornerstone for Creso Pharma’s global commercialization strategy using Switzerland as a reference country”. Creso fell two cents or two percent to 99.5 cents with 4.1 million shares traded.

NOXOPHARM

Noxopharm says it has provided NOX66 under its compassionate use scheme to a patient that has shown an “abscopal response”.

Noxopharm said that it had “become aware of information circulating in the market about an abscopal anti-cancer response in a patient receiving ... [it] experimental drug, NOX66”. The company said the patient had “given permission for the company to confirm that there has been a response from the combined use of NOX66 and a low dosage of radiotherapy, including a response in areas that were not irradiated [that is] an abscopal response”.

Noxopharm said that compassionate use was only available where patients were not eligible for a clinical trial and all other treatment options had been exhausted.

Noxopharm climbed 8.5 cents or 9.2 percent to \$1.005.

VIRALYTICS

Morgan Stanley and Mitsubishi UFJ say they have “collateral returned” 1,412,976 shares reducing last week’s substantial shareholding in Viralytics to below five percent.

Last week, Morgan Stanley and Mitsubishi UFJ Financial Group said they had become substantial shareholders in Viralytics with 12,686,219 shares or 5.27 percent, with the shares held under a “global master securities lending agreement” (BD: Dec 1, 2017).

Today, the companies said they bought 9,395 shares for \$6,036 or 64.2 cents a share and “returned” the 1,412,976 shares.

Viralytics was up five cents or 7.5 percent to 71.5 cents.

VIRALYTICS

Cormorant Healthcare says it has reduced its substantial shareholding in Viralytics from 15,019,987 shares (6.24%) to 12,500,000 shares (5.19%).

Cormorant said it sold shares between November 14 and 29, 2017 with the single largest sales 1,253,262 shares for \$1,021,409 or 81.5 cents a share.

GENETIC TECHNOLOGIES

Renaissance Technologies says a coding error related to algorithmic trading delayed filing its initial substantial shareholder notice for Genetic Technologies.

The New York-based Renaissance told the ASX that it became substantial in Genetic Technologies on March 9, 2017 and the reporting system had been “updated appropriately to correct the coding error”.

Renaissance said it held 148,392,000 shares or 6.09 percent of Genetic Technologies, buying shares in batches from 100 shares to 1,200 shares at prices from 1.1236 cents to 1.3373 cents a share between July 31 and September 13, 2017.

Genetic Technologies fell 0.1 cents or 11.1 percent to 0.8 cents with 1.9 million shares traded.

ADHERIUM

In an Appendix 3Z Final Director's Interest Notice, Adherium founder Garth Sutherland said he was leaving the company he founded.

In 2015, Adherium raised \$35 million to list on the ASX to commercialize its Smartinhaler asthma puffer monitor (BD: Aug 27, 2015).

In June, Adherium said Arik Anderson would replace Mr Sutherland as chief executive officer with Mr Sutherland continuing as an executive director (BD: Jun 9, 2017).

In October, on page five of the 14 page notice of annual general meeting under explanatory notes, Adherium said "Mr Sutherland has advised that he will be retiring as an executive director from the board at the 2017 AGM".

Adherium was up 0.3 cents or four percent to 7.8 cents.

TELIX PHARMACEUTICALS

Telix says it has appointed Dr Bernard Lambert as the president and chief operating officer of its US subsidiary Telix Pharmaceuticals (US) Inc.

Telix said the US subsidiary was a Delaware corporation established in October 2017 to support US clinical and manufacturing activities and establish a commercial footprint in the US.

Telix chief executive officer Dr Christian Behrenbruch said that Dr Lambert was "one of the most experienced radiopharmaceutical development executives in the United States".

The company said that Dr Lambert would manage the US manufacturing infrastructure, providing operational support for US-based clinical trials and establishing the team to support commercialization objectives in renal and prostate cancer imaging.

Telix said that Dr Lambert was previously Zevacor Molecular's and IBA Molecular's head of chemistry manufacturing control and radiopharmaceutical development and led the manufacturing of 124I-girentuximab, the predecessor to Telix's renal cancer imaging product, which was the subject of a phase III trial by Willex AG.

The company said that Dr Lambert held a Bachelor of Science and a Doctorate of Philosophy in chemistry from the University of Liège.

Telix was up 0.5 cents or 0.8 percent to 62.5 cents.

IMUGENE

Imugene says it has appointed Prof Peter Schmid to its scientific advisory board.

Imugene said that Prof Schmid was an oncologist at London's St Bartholomew's Hospital chair of cancer medicine at Queen Mary University London.

The company said that Prof Schmid's specialist cancer interests were breast and lung cancer, cancer immune therapy and early drug development.

Imugene said that Prof Schmid had led more than 20 academic clinical studies and had authored or co-authored 165 publications and published a book on the management of bone metastases.

Imugene fell 0.2 cents or 10 percent to 1.8 cents with 9.2 million shares traded.