



Biotech Daily

Thursday December 14, 2017

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: DIMERIX UP 8%; GENETIC SIGNATURES DOWN 12%**
- * **PHARMAXIS PAYS \$9m TO TAKE-BACK LOXL2 FROM SYNAIRGEN**
- * **PROTEOMICS, DIMERIX PARTNER FOR KIDNEY DISEASE**
- * **TELIX, SLOAN KETTERING PARTNER FOR KIDNEY CANCER**
- * **CYNATA RECEIVES \$1.3m FEDERAL R&D TAX INCENTIVE**
- * **HYDROPONICS RAISES \$8m, PLAN FOR \$3m MORE**
- * **ALLEGRA TO DISTRIBUTE WALDEMAR LINK JOINT REPLACEMENTS**
- * **NOXOPHARM PLEADS SCHULTZ, NEWS TO ASX 83% QUERY; FALLS 24%**
- * **BIOXYNE: 'NEW IMAGE GROUP \$1m CLAIM WITHOUT FOUNDATION'**
- * **JCP BELOW 5% OF VIRALYTICS**
- * **CRYOSITE, CELL CARE ASSET SALE, SHARE BUY-BACK EGM**
- * **MGC TO LAUNCH MARIJUANA HERBAL REPAIR CREAM FOR PSORIASIS**
- * **CRESO PHARMA REQUESTS 'LATIN AMERICA ACQUISITION' HALT**
- * **DR JAY HETZEL REPLACES UNIQUEST CHAIR MARY BOYDELL**
- * **ALCIDION APPOINTS KEVIN MOYNIHAN FOR BUSINESS DEVELOPMENT**

MARKET REPORT

The Australian stock market fell 0.17 percent on Thursday December 14, 2017 with the ASX200 down 10.5 points to 6,011.3 points. Eleven of the Biotech Daily Top 40 stocks were up, 17 fell, 11 traded unchanged and one was untraded. All three Big Caps fell.

Dimerix was the best, up one cent or 8.3 percent to 13 cents with 84,311 shares traded. Both Medical Developments and Polynovo improved 2.4 percent; with Airxpanders, Avita, ITL, Nanosonics, Neuren, Orthocell, Sirtex and Viralytics up more than one percent.

Genetic Signatures led the falls, down four cents or 11.8 percent to 30 cents with 106,000 shares traded. Prana lost 6.85 percent; Actinogen, Admedus, Factor Therapeutics, Immutep (Prima) and Volpara fell four percent or more; Mesoblast, Oncosil and Osprey were down more than three percent; Clinuvel, LBT, Opthea and Starpharma shed more than two percent; Ellex, Impedimed, Pro Medicus and Resmed were down one percent or more; with Cochlear and CSL down by less than one percent.

PHARMAXIS

Pharmaxis says it has “taken full scientific and commercial control” of the lysyl oxidase type 2 [LOXL2] collaboration with the Southampton, England-based Synairgen PLC. Pharmaxis began the collaboration with Synairgen in 2015 to develop a selective inhibitor to the lysyl oxidase type 2 enzyme to treat the lung disease idiopathic pulmonary fibrosis (BD: Aug 5, 2015).

Today, the company said that it would pay Synairgen GBP5 million (\$A8.75 million) to resume full control over the assets and reduce Synairgen’s stake in any partnership from about one third of up-front fees, milestones and royalties to 17 percent.

In April, Synairgen told the London Stock Exchange that Astrazeneca had handed back AZD9412, or inhaled interferon beta, for chronic obstructive pulmonary disease and later said the drug, renamed SNG001, would be the subject of a clinical trial in the 2017-’18 Northern Hemisphere Winter.

In September, Synairgen said its operating loss for the six months to June 30, 2017 was GBP1.58 million and had cash and bank deposits of GBP3.08 million.

Today, Pharmaxis chief executive officer Gary Phillips told Biotech Daily that Synairgen would have the rights to 17 percent of any partnering agreement including up-front fees, milestones and royalties, which was a reduction from the previous agreement which was for “about one third” of all payments.

“Strategically we have taken back the drug and they have received GBP5 million [\$A8.75 million) to pursue the Astrazeneca asset, so it is a win-win,” Mr Phillips.

Mr Phillips said that several companies were interested in potential partnerships for the LOXL2 program for non-alcoholic steato-hepatitis, or fatty liver disease.

In a media release, Pharmaxis said it had “doubled the program scope” to encompass two lead candidates that it intended to take to the end of phase I trials with additional toxicology data to enable them to be phase II ready by mid-2018.

The company said it hoped to conclude a deal after the phase I studies reported.

Pharmaxis said the LOXL2 enzyme was “fundamental to the progression of fibrosis” in the liver disease non-alcoholic steato-hepatitis, as well as fibrotic disease in organs such as the heart, kidney and lung, where idiopathic pulmonary fibrosis had a high unmet need.

The company said the collaboration’s pre-clinical program identified two compounds with “all the characteristics of successful once-a-day, oral drugs, showing excellent efficacy in several different in-vivo fibrosis models” with toxicity studies showing both to be well-tolerated and with good safety profiles.

Pharmaxis said the LOXL2 inhibitor program was the subject of discussions with large pharmaceutical companies and it expected that interest “to intensify as the two compounds progress through phase I clinical trials and report in mid-2018”.

Mr Phillips said Synairgen pre-clinical collaboration had “served its purpose very well, however, the increased interest in [non-alcoholic steato-hepatitis] together with Pharmaxis’ progress over the last few years, its track record of delivering significant partnering deals and enhanced financial position, means we are now in a position to develop this product under our control with our own resources so that we can maximise shareholder value”.

“Ongoing discussions with multinational pharma companies suggest that there is a significant opportunity for an oral once a day LOXL2 inhibitor in a number of fibrotic diseases with a high unmet need,” Mr Phillips said.

“We will use our strong cash position to fully meet the needs of our potential partners,” Mr Phillips said.

In its most recent Appendix 4C quarterly report, Pharmaxis said it had \$38,629,000 in cash and cash equivalents at September 30, 2017.

Pharmaxis was unchanged at 26 cents.

TELIX PHARMACEUTICALS

Telix says it will collaborate with New York's Memorial Sloan Kettering Cancer Centre on its TLX-250 "molecularly targeted radiation" for clear cell renal, or kidney, cancer.

Telix said it was developing TLX-250 for imaging renal cancer with positron emission tomography technology and Sloan Kettering would use the TLX-250 as a tool "to better manage the therapeutic algorithm" by assessing early treatment response to standard care drugs for patients with metastatic clear cell renal cancer.

Telix chief executive officer Dr Christian Behrenbruch said Telix believed that "treatment-response imaging with TLX-250 [could] fundamentally change the way we cycle patients through tyrosine kinase inhibitors, mTOR inhibitors and [vascular endothelial growth factor]-targeting drugs to more recently available options such as nivolumab".

"In doing so it is hoped that we can do a better job of maximizing therapeutic response for patients with advanced disease," Dr Behrenbruch said.

Sloan Kettering's Dr Steven Larson said clinical trials for the iodine-124 antibody, the precursor for TLX-250, began more than a decade ago at Sloan Kettering and the development of TLX-250 would bring the program "full circle".

Telix said it would fund Sloan Kettering's implementation of a new radiochemistry process and would amend the existing study protocol for repeat dosing of iodine-124 "to take advantage of the superior sensitivity and specificity" of using zirconium-89 in the detection of smaller lesions that were "often challenging to image with iodine chemistry".

The company said that under the agreement, it would provide clinical-grade material to Sloan Kettering and "modest financial support for the radiochemistry upgrade", and the agreement included clinical data sharing.

Telix was unchanged at 61 cents.

DIMERIX, PROTEOMICS INTERNATIONAL

Proteomics and Dimerix says they will partner to evaluate the Promarkerd test in clinical trials for the DMX-200 treatment for chronic kidney disease.

Dimerix and Proteomics said that Promarkerd had the potential to serve as a companion diagnostic test in clinical trials to help measure and monitor the effectiveness of DMX-200, helping to identify at risk patients who might benefit from the drug, enable more accurate dosing and help monitor clinical end points and side effects.

Dimerix said it expected the Promarkerd test to be used in its current phase I pharmacokinetic study in Perth and a planned phase II trial program.

Proteomics said that Promarkerd had been shown in clinical studies to predict rapid decline in kidney function up to four years in advance.

In July, Dimerix said that its 27-patient, phase IIa trial of DMX-200 for chronic kidney disease had met its safety primary endpoint and showed efficacy in a meaningful number of patients (BD: Jul 12, 2017).

Dimerix was up one cent or 8.3 percent to 13 cents.

Proteomics fell one cent or four percent to 24 cents.

CYNATA THERAPEUTICS

Cynata says it has received \$1,328,649 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Cynata said that Federal R&D Tax Incentive refund related to expenditure in the year to June 30, 2017.

Cynata was up one cent or 1.7 percent to 61 cents.

THE HYDROPONICS COMPANY

Hydroponics says it has raised \$8 million in a placement at 63 cents a share and hopes to raise a further \$3 million in a share plan.

Hydroponics said that the offer price was a 19.8 percent discount to the 5-day volume-weighted average price.

The company said the funds were “to expand both its Canadian and Australian businesses ... to fast-track domestic development of medicinal cannabis for Australian patients, further investment into Canadian assets and provide necessary working capital”. Hydroponics said the placement was “fully-subscribed” with seven new institutional investors joining the register.

The company said that directors would take their full allocation in the share plan, with investors able to apply for parcels of shares up to \$15,000, with a record date of December 13, opening on December 20, 2017 and closing on January 19, 2018. Hydroponics fell 10 cents or 12.7 percent to 69 cents with 1.4 million shares traded.

ALLEGRA ORTHOPAEDICS

Allegra says it has a three year agreement to distribute Waldemar Link GmbH medical device implant products in Australia with an option to extend to five years.

Allegra said that the Hamburg, Germany-based Waldemar Link distributed its joint replacement products in more than 60 countries.

Allegra was untraded at 15 cents.

CRYOSITE

Cryosite shareholders will vote to sell “certain assets relating to its cord blood and tissue banking business to Cell Care Australia Pty Ltd.

Cryosite said a second resolution proposed buying-back 9,229,995 shares from Cell Care Australia.

In 2015, Cellcare said it held 9,229,995 Cryosite shares or 19.79 percent of the company (BD: Nov 26, 2015).

In August, the Australian Competition and Consumer Commission said it was reviewing a proposed Cryosite licence and sale of assets to Cell Care (BD: Aug 4, 2017).

The meeting will be held at 13A Ferndell Street, South Granville, New South Wales on January 15, 2018 at 10.30am (AEDT).

Cryosite was unchanged at 13.5 cents.

NOXOPHARM

Noxopharm has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company’s share price rose 81.5 cents or 82.7 percent from 98.5 cents on December 7 to \$1.80, today December 14, 2017, and noted “a significant increase” in the trading volume.

Noxopharm told the ASX that it had “made some significant positive ASX releases recently”.

Noxopharm fell 38 cents or 24.05 percent to \$1.20 with 1.3 million shares traded.

BIOXYNE

Bioxyne says that New Image Group has filed a \$1.1 million statement of claims against it in the High Court of New Zealand on December 5, 2017.

Bioxyne said that its annual report of September 25, 2017 disclosed “advice from a third party alleging misuse of confidential information in our direct sales marketing plan”.

The company said the allegations were vigorously rejected and discussions were ongoing. The single paragraph statement was on page eight of the 59-page announcement to the ASX.

Bioxyne said that with wholly-owned subsidiary Bioxyne International (NZ) and managing-director Nam Hoat Chua it had been notified but not served with a statement of claims by New Zealand’s New Image Group.

The company said its New Zealand solicitors had not accepted service of the notice of the claim, pending a determination as to jurisdiction.

Bioxyne said the claim sought damages of about \$NZ1.2 million (\$A1.1 million) “for misleading and deceptive conduct, and an injunction against using the plaintiff’s confidential information, approaching the plaintiff’s distributors and comparing the company’s marketing plan with the plaintiff’s marketing plan”.

The company said the “claims are without foundation and will be vigorously defended”.

Bioxyne said that when the statement of claim was served on each of the defendants properly, it would file a statement of defence within the required 25 business days.

The company said that Auckland’s Kensington Swan was its law firm.

Bioxyne was up 0.4 cents or 4.65 percent to nine cents with 11.2 million shares traded..

VIRALYTICS

JCP Investment Partners says it has ceased its substantial shareholding in Viralytics.

Last year, the Melbourne-based JCP said it had become a substantial shareholding with 12,181,035 shares or 5.07 percent, with the single largest purchase 2,815,000 shares for \$3,102,461 or \$1.10 a share (BD: Dec 6, 2016).

Today, JCP said that between December 5, 2016 and December 12, 2017 it bought, sold and transferred shares, with the single largest sale 234,257 shares for \$152,665 or 65.2 cents a share.

Viralytics was up one cent or 1.7 percent to 60 cents.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says it will launch its first marijuana-based Derma Plus Herbal Repair Cream for mild psoriasis on January 1, 2018.

MGC said the cream used “proprietary cannabidiol compounds ... for the daily treatment of mild forms of psoriasis symptoms” with independent tests showing a reduction of skin irritation by 69 percent after four weeks, skin itchiness, flaking and severe dryness.

MGC was up 0.4 cents or 5.3 percent to eight cents with 8.2 million shares traded.

CRESO PHARMA

Creso has requested a trading halt “pending an announcement in relation to significant acquisition in Latin America”.

Trading will resume on December 18, 2017, or on an earlier announcement.

Creso last traded at 83 cents.

UNIQUEST

Uniquet says it has appointed scientist and investor Dr Jay Hetzel as its chairman replacing Mary Boydell.

Uniquet is the University of Queensland's commercialization company and chief executive officer Dr Dean Moss said Dr Hetzel "brought a wealth of experience in life sciences research, product development and commercialisation".

Dr Moss said that Dr Hetzel worked in animal genetics and genomics research at the Commonwealth Scientific and Industrial Research Organisation for more than 20 years and co-founded Genetic Solutions in 1998 to commercialize genomics technology in livestock, selling the company to Pfizer Animal Health in 2008.

Uniquet said that Dr Hetzel had worked on commercializing bio-based products in early-stage ventures and was currently chairman of Leaf Resources and a director of Anantara Lifesciences.

Uniquet said that Ms Boydell had been a director for six years and "made a significant contribution to the governance and strategic framework underpinning Uniquet's ongoing commercial success".

The company said that Dr Hetzel held a Bachelor of Agricultural Science from the University of Melbourne and a Doctorate of Philosophy from the University of Sydney.

ALCIDION GROUP

Alcidion says it has appointed Kevin Moynihan as its head of business development.

Alcidion said that Mr Moynihan was a health information technology executive and founder of Kestral Computing.

The company said that Mr Moynihan would "manage emerging business initiatives and help identify new growth opportunities", with an initial focus on its Miya Cloud AI, analytics platform, its new revenue/safety modules and the recently acquired Smartpage product set.

Alcidion said that following the acquisition of Kestral Computing by Constellation Software in 2012, Mr Moynihan continued as its chief executive officer until July 2017.

Alcidion was up 0.2 cents or four percent to 5.2 cents.