Biotech Daily

Monday May 18, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PHARMAXIS UP 52%, ANTISENSE DOWN 19%**

*** PHARMAXIS $750m+ BOEHRINGER DEAL FOR PXS4728A FOR NASH**

*** BRANDON, MRCF, UNISEED $6.5m FOR OCCURX FOR OCULAR FIBROSIS**

*** ADMEDUS TO LAUNCH CARDIOCEL REPAIR PATCH**

*** NANOSONICS KILLS HPV ON TRANS-VAGINAL ULTRASOUND PROBES**

*** MAYNE COMPLETES HEDGEPATH SUBA-ITRACONAZOLE LICENCE**

*** BENITEC HEP C ddRNAi US PATENT GRANTED, EURO PATENT ALLOWED**

*** BIOTECH ADVISORY IQ3 OPENS UP 17%, CLOSES UP 67%, RAISES $4m**

*** CBA, RELATED PARTIES BUY, BORROW 6% OF SIRTEX**

*** BLUECHIIP PLEADS SCHULTZ TO ASX 33% QUERY**

*** BIONOMICS: DR JENS MIKKELSEN CSO, JACK MOSCHAKIS LEGAL, CO SEC**

MARKET REPORT

The Australian stock market fell 1.33 percent on Monday May 18, 2015 with the S&P ASX 200 down 76.3 points to 5,659.2 points. Fourteen of the Biotech Daily Top 40 stocks were up, 16 fell, seven traded unchanged and three were untraded. All three Big Caps fell.

Pharmaxis was the best, up 8.5 cents or 51.5 percent to 25 cents with 43.4 million shares traded, followed by Nanosonics up 12.0 percent to $1.77 with 2.6 million shares traded. Admedus climbed 4.2 percent; Actinogen, Living Cell and Prana were up more than three percent; Atcor, Bionomics, Compumedics, IDT, Starpharma and Viralytics rose two percent or more; Psivida was up 1.9 percent; with Clinuvel up 0.6 percent.

Antisense led the falls, down 2.5 cents or 19.2 percent to 10.5 cents with 934,463 shares traded, followed by GI Dynamics down 10.3 percent to 13 cents with 240,000 shares traded. Oncosil lost 8.7 percent; Benitec was down 6.1 percent; Analytica and Genetic Technologies fell more than five percent; Ellex and Prima were down more than four percent; Sirtex was down 3.2 percent; Impedimed, Neuren, Optiscan and Tissue Therapies shed more than two percent; Acrux, CSL, Osprey and Resmed were down more than one percent; with Cochlear and Mesoblast down by less than one percent.

PHARMAXIS

Pharmaxis says Boehringer Ingelheim will pay an upfront fee of $39.2 million and potentially more than $750 million for PXS4728A for non-alcoholic steato hepatitis.

Pharmaxis said that the Ingelheim, Germany-based Boehringer exercised its option and acquired PXS4728A to develop it for the treatment of non-alcoholic steato hepatitis (NASH) and to prevent its consequences.

The company said that it discovered PXS4728A which was a semicarbazide-sensitive amine oxidase vascular adhesion protein-1 (SSAO/VAP-1) inhibitor that worked by blocking leucocyte adhesion and tissue infiltration in inflammatory processes.

Pharmaxis said it had developed the compound through to phase I clinical studies, demonstrating oral bioavailability, long-lasting target inhibition and good tolerability and safety.

The company said that NASH was the progressive form of non-alcoholic fatty liver disease, the most common liver disorder in Western industrialized nations and regarded as a major cause of fibrosis and cirrhosis of the liver and was an area of high unmet clinical need.

Pharmaxis said that the high prevalence of type 2 diabetes and obesity, which could lead to NASH and its long term consequences was considered to make NASH one of the most common causes of advanced liver disorders in coming decades.

Pharmaxis chief executive officer Gary Phillips said the deal with Boehringer was “a transformational event for Pharmaxis”.

“With a total potential value in excess of $750 million, it is a globally competitive deal and significant for the Australian biotech sector,” Mr Phillips said.

“We are delighted that Boehringer Ingelheim, a leader in cardiometabolic research and development, has acquired PXS4728A,” Mr Phillips said.

“Boehringer Ingelheim’s clinical expertise will now be applied to the development of this drug which has the potential to make a real difference in the treatment of diseases with high unmet clinical need,” Mr Phillips said.

Boehringer Ingelheim’s head of metabolism and corporate senior vice-president Glyn Parkin said the company has “ambitious strategic goals in diabetes and metabolism and this phase I asset acquisition fits well into our development portfolio”.

“We are pleased to have achieved access to Pharmaxis’ research excellence and innovative approach to treatments for NASH,” Mr Parkin said.

Pharmaxis said it would receive an upfront payment of EUR27.5 million ($39.2 million) and subject to continuing development and commercialization of the PXS4728A program up to a total of EUR55 million ($A78.4 million) in development milestone payments tied to the commencement of phase II and III clinical trials; up to a total of EUR140 million ($A199.5 million) in regulatory milestone payments upon filing of applications for marketing approval and receipt of regulatory and pricing approvals for a PXS4728A program product in the major pharmaceutical markets of the US, EU, and China or Japan for the first indication; additional milestone payments for the achievement of the same development and regulatory milestone events by a PXS4728A program product for a second indication; earn-out payments on annual net sales of PXS4728A program products at tiered percentages starting in the high single digits; and commercialization milestone payments on achievement of specified levels of annual net sales of PXS4728A program products.

Pharmaxis said that Boehringer would be responsible for all development, regulatory, manufacturing and commercialization activities.

The company said that Boehringer had acquired other SSAO/VAP-1 inhibitor molecules related to PXS4728A and associated patents.

Pharmaxis climbed 8.5 cents or 51.5 percent to 25 cents with 43.4 million shares traded.

OCCURX

Occurx says that it will receive $6.5 million from the Medical Research Commercialisation Fund, Brandon Capital and Uniseed to develop a new class of drugs for ocular fibrosis.
The Melbourne-based Occurx said it had established pre-clinical proof-of-concept with its lead anti-fibrotic compound in an animal model of ocular inflammation and fibrosis.
The company said that its primary focus was the development of innovative therapeutic strategies for the treatment of ophthalmic disorders associated with retinal fibrosis and inflammation.
Occurx chief executive officer Dr Darren Kelly said that the venture capital from the consortium provided “a strong position at the start of our corporate journey with secure funding and an advancing portfolio of products”.
“Now that we have established proof-of-concept we will be advancing our lead product into the clinic early next year,” Dr Kelly said.
Dr Kelly was formerly the chief executive officer of Fibrotech, which was sold to Shire Pharmaceuticals for an upfront fee of $US75 million in a deal believed to be valued at more than $600 million (BD: May 2, 2014).
Brandon Capital managing director Dr Chris Nave said the group was “extremely excited by the company’s intellectual property and preliminary data and have every confidence that Dr Kelly and his team have what it takes to make Occurx a huge success”.
“It is testament to his previous efforts and the success of the [Medical Research Commercialisation Fund] model that one of our earliest investments in Dr Kelly’s first company Fibrotech resulted in one of Australia’s most eye-catching life science acquisition transactions,” Dr Nave said.
“We are delighted to be partnering with Darren and his team again,” Dr Nave said.
Brandon Capital is the manager of the Medical Research Commercialisation Fund
Uniseed chief executive officer Dr Peter Devine said that “on the back of Uniseed’s successful exit from Fibrotech last year, we are thrilled to provide further support for the cutting edge translational research performed by Dr Kelly’s team at the University of Melbourne”.
Occurx is a private company.

ADMEDUS

Admedus says it has it will launch a 2cm by 8cm Cardiocel tissue patch for vascular repairs such as carotid endarterectomies in the US in June 2015.
Admedus said that the new patch was part of the strategy to expand the use of the Adapt-treated bovine cardiac tissue Cardiocel across a range of surgical applications.
Admedus chief executive officer Lee Rodne said that the new Cardiocel product was “part of Admedus’ plan to build an Adapt tissue franchise, providing surgeons with a range of products for surgical repairs”.
The company said that as well as the use of Cardiocel for cardiac repairs and reconstructions, it had been used in 10 cases of vascular repair, including carotid endarterectomies and femoral artery repairs in the US.
Admedus said that the use of Cardiocel in vascular applications was within the current indication for the US and the vascular repair market was a significant potential market with an estimated 180,000 carotid endarterectomies performed each year.
Admedus said that Cardiocel was used in 31 European and 35 US centers and more than 70 centers globally, with more than 1800 patients implanted with the patch.
Admedus was up 0.3 cents or 4.2 percent to 7.4 cents with 9.7 million shares traded.

NANOSONICS

Nanosonics says that a study has shown that its Trophon EPR is the only ultrasound probe disinfection system effective against strains of human papillomavirus (HPV).

Nanosonics said that the study, entitled 'Efficacy of a high-level disinfectant system against high-risk human papilloma virus' was co-authored by technology development and commercialization president Dr Ron Weinberger and presented at the Society for Healthcare Epidemiology of America in Orland, Florida from May 14 to 17, 2015.

The study summary is available at: http://bit.ly/1HbQpIX.

The company said that the study showed that the Trophon EPR was the only disinfectant to completely inactivate human papillomavirus virus.

Nanosonics said that high-risk human papillomavirus virus accounted for five percent of all cancers worldwide and was responsible for almost all cases of cervical cancer and was a leading cause of oral, throat, anal and genital cancers.

The company said that previous studies had demonstrated the human papillomavirus virus transmission risk from ultrasound probes, with between three and seven percent of probes used in trans-vaginal examination were contaminated with human papillomavirus virus, despite the use of probe covers and routine disinfection with wipes.

Nanosonics said that there had not been a good mechanism to test the effectiveness of various disinfectants against real, infectious human papillomavirus virus, but researchers from Pennsylvania State College of Medicine and the Provo, Utah-based Brigham Young University had developed a method to grow sufficient infectious human papillomavirus virus particles to determine the effectiveness of various disinfectants.

The company said that the researchers carried out a study, published last year, looking at the effectiveness of the disinfectants glutaraldehyde and ortho-phthalaldehyde, which were commonly used on ultrasound probes and found both disinfectants failed to inactivate natural, infectious, high-risk HPV16 after 24 hours of contact time.

Nanosonics said the results led to the study in which ortho-phthalaldehyde, hypochlorite and the Trophon EPR device were tested against HPV16 and HPV18, the major cancer-causing types of HPV.

Pennsylvania State professor of microbiology and immunology Prof Craig Meyers said that "disinfectant efficacy testing was not previously possible until we developed a method to grow sufficient infectious HPV particles for research".

"Without a means to test the natural, infectious form of HPV, the susceptibility of disinfectants has remained unknown," Prof Meyers said.

"Our first study showed that neither glutaraldehyde nor ortho-phthalaldehyde were effective against HPV while this new study found that Trophon EPR was completely effective," Prof Meyers said.

"The concern is that these other liquid chemical disinfectants are commonly used in medical and healthcare facilities," Prof Meyers said. "Where this is happening, HPV is not being killed, posing a risk for transmission."

Nanosonics said the study concluded that the results should be considered when selecting disinfection methods and a review of standards might be warranted.

Nanosonics chief executive officer Michael Kavanagh said the results were "clinically very significant and emphasize the importance of effective reprocessing of ultrasound probes to minimize the risk of cross contamination".

"The outcomes of this study along with ongoing clinical work we are conducting further supports our objective of establishing Trophon EPR as the new standard of care for the high level disinfection of ultrasound probes," Mr Kavanagh said.

Nanosonics climbed 19 cents or 12.0 percent to $1.77 with 2.6 million shares traded.

MAYNE PHARMA GROUP

Mayne Pharma says it will invest $US2.5 million in investee company Hedgepath Pharmaceuticals to accelerate development of Suba-itraconazole for cancer.

Last year, Mayne out-licenced its Suba-itraconzaole to the Tampa, Florida-based Hedgepath for a 41.5 percent equity stake, saying Hedgepath had secured further funding for the clinical development, registration and commercialization of the oral formulation of itraconazole, for the treatment of a variety of cancers in the US, and was separate to Mayne commercializing Suba-itraconazole for fungal infections (BD: Jun 25, 2014).

In 2010, Mayne Pharma (then Halcygen) completed a 175-patient, phase II US study showing Suba-itraconazole superiority over itraconazole for fungal infections and in 2013, Mayne said it had UK approval and had begun two US pivotal studies of Subacap (Suba-itraconazole) for fungal infections (BD: Apr 13, 2010; Dec 15, 2011; Jun 17, 2013).

Today, Mayne said the new investment would take its share of Hedgepath to 49.4 percent and if it exercised related options it would hold to 51.1 percent on a fully diluted basis.

Mayne Pharma said that a phase IIb study in patients with basal cell carcinoma nevus syndrome, or Gorlin's syndrome, would begin by July 2015 with preliminary results expected early in 2016.

The company said that US Food and Drug Administration cleared trial design was a 40-patient, single arm, phase IIb, multi-centre, open-label, non-placebo-controlled study.

Mayne said that Gorlin's syndrome resulted from a genetic mutation, which caused the Hedgehog signaling pathway to function improperly leading to the chronic formation of basal cell tumors.

The company said that there were about 10,000 patients in the US with Gorlin's syndrome, and Suba-Itraconazole could potentially qualify for orphan drug designation.

Mayne said that if the study achieved the expected clinical end points, Hedgepath planned to begin discussions with the FDA to see if the results could serve as the basis for a new drug application.

The company said that Hedgepath would consider broadening the development program to include other cancer types including selected lung and prostate cancers.

Mayne chief executive officer Scott Richards said the evidence supporting itraconazole in cancer was "well-established and we believe our Suba-itraconazole product provides a number of advantages over conventional itraconazole, including improved bioavailability and more consistent blood levels to improve the therapeutic effect".

Mayne fell 2.5 cents or 2.2 percent to $1.125 with 1.6 million shares traded.

BENITEC BIOPHARMA

Benitec says that the US Patent Office has granted a patent entitled 'RNAi expression constructs'.

Benitec said that the patent claimed DNA-directed RNA-interference (ddRNAi) expression constructs comprising multiple short hairpin RNA (shRNA) sequences targeting hepatitis C, driven off a single promoter.

The company said it was the third US patent granted in this family, further strengthening the intellectual property protection for Benitec's hepatitis C program until 2026 in the US.

Benitec said that the European Patent Office had allowed the corresponding patent application in the patent family, the first European patent to be granted in this family.

The company said that the EPO would announce the grant of the application and set a deadline of nine months for third parties to oppose the patent.

Benitec said that in the absence of any opposition, the patent would be granted.

Benitec fell five cents or 6.1 percent to 76.5 cents.

IQ3 CORP

Corporate finance and advisory firm IQ3 opened at 35 cents, a 16.7 percent premium to its initial public offer at 30 cents a share, saying it raised $4.4 million (BD: Apr 23, 2015).
IQ3 closed up 20 cents or 66.7 percent at 50 cents with 339,180 shares traded.

SIRTEX MEDICAL

The Commonwealth Bank of Australian and a large number of related parties have bought and borrowed 3,534,663 shares or 6.15 percent.
The CBA named scores of related companies and said that between January 12 and May 14, 2015 it had acquired the shares in a large number of trades requiring more than 100 pages to report the trades, with some shares subject to share lending agreements.
Sirtex fell 90 cents or 3.2 percent to $27.10 with 855,644 shares traded.

BLUECHIIP

Bluechiip 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 1.8 cents or 32.7 percent from 5.5 cents on May 14 to 7.3 cents on May 15, 2015, but did not note an increase in trading volume.
Bluechiip fell 0.4 cents or 5.3 percent to 7.1 cents with 1.5 million shares traded.

BIONOMICS

Bionomics says it has appointed Dr Jens Mikkelsen as its chief scientific officer and Jack Moschakis as its legal counsel and company secretary.
Bionomics said that Dr Mikkelsen had "extensive experience in neuroscience" and was a co-founder of the Glostrup, Denmark-based Zealand Pharmaceuticals, whose first drug was lixisenatide marketed as Lyxumia, a type 2 diabetes treatment, licenced to Sanofi.
The company said that Dr Mikkelsen had roles in drug discovery at central nervous system (CNS) pharmaceutical company Lundbeck AS.
Bionomics said that Dr Mikkelsen's work had been published in 285 peer-reviewed scientific journals specializing in neuroscience and neuro-pharmacology and he had more than 20 patents for drugs used for CNS and metabolic disorders.
The company said that Dr Mikkelsen held a Degree in Medicine as well as a Doctorate of Medical Science and was currently professor in translational neuropharmacology at the Neurobiology Research Unit, University Hospital of Copenhagen.
Bionomics said that Mr Moschakis had more than 25 years experience as a legal practitioner and had worked in senior legal and company secretary roles in the South Australian electricity industry for more than 10 years, with expertise in energy law and energy-related commercial and contractual matters and was most recently Rex Minerals legal consultant.
The company said that Mr Moschakis held a Bachelor of Economics and a Graduate Diploma in Business Administration from the University of Adelaide, as well as a Diploma in Law from the University of New South Wales.
Bionomics was up one cent or 2.4 percent to 42 cents.