Biotech Daily

Thursday October 11, 2018

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PHARMAXIS UP 3.45%; VOLPARA DOWN 14%**

*** PHARMAXIS: LOXL2 DRUG 'HIGHLY MEANINGFUL ENZYME INHIBITION'**

*** SAUDI ARABIA APPROVES MEDICAL DEVELOPMENTS PENTHROX**

*** RESAPP CLAIMS SLEEP APNOEA ALGORITHMS '90% ACCURATE'**

*** ORTHOCELL RECEIVES $2.5m FEDERAL R&D TAX INCENTIVE**

*** CARDIEX: CEO CRAIG COOPER, DIRECTOR NIALL CAIRN $1.5m**

*** ZELDA ENDS CHILE MARIJUANA RESEARCH PROGRAM**

*** TGA APPROVES MGC MARIJUANA CANNEPIL FOR EPILEPSY**

*** CVC TAKES 12% OF UNIVERSAL BIOSENSORS**

*** SIMAVITA: POST-PLACEMENT SUBSTANTIAL HOLDERS IN, OUT, DILUTED**

*** SUDA APPOINTS ANDREW CURTIS FOR US BUSINESS DEVELOPMENT**

*** CLARITY APPOINTS PROF JASON LEWIS TO ADVISORY BOARD**

MARKET REPORT

The ASX followed the US, down 2.74 percent on Thursday October 11, 2018 with the ASX200 retreating 166.0 points to 5,883.8 points. Two of the Biotech Daily Top 40 stocks were up, 30 fell, four traded unchanged and four were untraded. All three Big Caps fell.

Pharmaxis was the better of the two rises, up one cent or 3.45 percent to 30 cents with 368,040 shares traded, while Prana improved 0.1 cents or two percent to five cents with 95,000 shares traded.

Volpara led the falls, down 17 cents or 13.9 percent to $1.05, with 928,646 shares traded. Avita lost 13.0 percent; Pro Medicus fell 11.0 percent; Imugene, Osprey and Prescient retreated more than nine percent; Opthea and Immutep were down more than eight percent; Bionomics, Nanosonics, Neuren and Starpharma shed more than seven percent; Airxpanders, Benitec, Mesoblast Telix and Uscom lost more than six percent; Clinuvel, Cochlear and Cynata fell more than five percent; Actinogen, Compumedics and Resmed lost more than four percent; CSL, Ellex, Genetic Signatures, Medical Developments and Paradigm were down three percent or more; Oncosil, Orthocell and Polynovo shed two percent or more; with Factor and Impedimed down more than one percent.

PHARMAXIS

Pharmaxis says its phase I trial of its first lysyl oxidase-like 2 inhibitor for fibrotic diseases is safe and “a large and highly meaningful inhibition” of the enzyme.

Pharmaxis said the double-blind, placebo-controlled study of the lysyl oxidase-like 2 (LOXL2) inhibitor compounds were targeting diseases including non-alcoholic steatohepatitis and idiopathic pulmonary fibrosis.

The company said the study began with a single-ascending dose in 48 healthy subjects in six groups receiving one dose of the compound ranging from 10mg to 400mg or placebo.

Pharmaxis chief executive officer Gary Phillips told Biotech Daily that the second multiple-ascending dose stage in 24 healthy had three groups receiving a single daily dose of 100mg, 200mg or 400mg of the compound for 14 days.

Mr Phillips said each group was blinded and comprised six volunteers receiving the drug and two receiving placebo.

The company said that “excellent drug-like properties [were] demonstrated in earlier pre-clinical testing were confirmed”.

Pharmaxis said there were “no adverse safety findings in either the first or second stages of the study and the pharmacokinetic profile showed the expected dose-related increases in exposure”.

“In addition to studying the safety and pharmacokinetic profile, the clinical trial also investigated the degree to which the drug can inhibit the target enzyme LOXL2 which is implicated in several different fibrotic diseases,” Pharmaxis said.

“Pharmaxis has been able to demonstrate a large and highly [non-statistically] significant inhibition of this enzyme in blood serum for a full 24 hours from a single dose and that daily dosing over a 14-day period now meets our targeted effect of greater than 80 percent inhibition at the 400mg dose,” the company said.

“We believe that the level of more than 80 percent inhibition will be clinically meaningful as well as statistically significant when trialled in patients in later phase studies,” Mr Phillips said.

In the media release to the ASX, Mr Phillips said the company was “delighted that the excellent pharmaco-kinetic parameters and the significant and long-lasting inhibition of the target LOXL2 enzyme demonstrated in the single dose stage of the study earlier this year completely translated into the profile we have seen in the multiple dosing study”.

“This drug profile has led to increased interest from major pharmaceutical companies looking for good anti fibrotic programs to acquire,” Mr Phillips said.

“Today’s announcement that enzyme inhibition is further enhanced after daily dosing over 14 days goes a long way to completing the data package on which we will base continuing scientific and commercial discussions with potential partners during the current quarter,” Mr Phillips said.

Pharmaxis said that a phase I trial for a second LOXL2 compound recently completed dosing and would be reported by the end of 2018.

The company said that LOXL2 program compounds were “highly selective small molecule inhibitors of LOXL2 that can be administered orally” which supported the potential of both compounds to treat fibrotic disease in several organs.

Pharmaxis said its assay technology showed target engagement in animal tissue from pre-clinical studies as well as serum, with 28-day animal toxicity studies completed in two species for both compounds and the remaining three-month studies due to be completed this year.

The company said that it had announced its intention to partner the LOXL2 program after phase I studies were completed.

Pharmaxis was up one cent or 3.45 percent to 30 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says that Saudi Arabia has granted marketing authorization for its Penthrox inhaled methoxyflurane analgesic for acute pain.

Medical Developments chief executive officer John Sharman said his company had worked with the Riyadh-based Yahmaa Medical Company since 2014 to have Penthrox approved.

"We expect the granting of this marketing authorization will … be a catalyst for a number of other country approvals in the Middle East," Mr Sharman said.

"Compared to Western … standards, patients in the Middle East are often undertreated for pain," Mr Sharman said.

"We understand [fewer] than 10,000 patients receive an opioid for the emergency relief of pain each year," Mr Sharman said.

Yahmaa director Dr Allam Al-Barazi said "a non-opioid, non-addictive, non-invasive, fast-acting, treatment option like Penthrox is necessary in the Kingdom of Saudi Arabia".

Medical Developments fell 18 cents or 3.6 percent to $4.77 with 759,871 shares traded.

RESAPP HEALTH

Resapp says its machine-learning algorithms have shown 90 percent accuracy in identifying obstructive sleep apnoea from breathing and snoring sounds.

Resapp said the algorithms provided a result for 554 of the 582 patients, in the prospective double-blind study, when measuring patients at the normal level on the apnoea hypopnea index (AHI), or five or more apnoea episodes an hour.

The company said the study found that at the index's normal level its algorithms displayed 84 percent sensitivity (accurate positives) and 83 percent specificity (accurate negatives) in identifying obstructive sleep apnoea from breathing and snoring sounds with an accuracy, or area under the curve, of 90 percent.

Resapp said that at the mild sleep apnoea level of 15 or more apnoea events an hour, its algorithms displayed 80 percent sensitivity and 80 percent specificity with an accuracy, or area under the curve, of 88 percent and, at the moderate sleep apnoea level of 30 or more apnoea events an hour, its algorithms displayed 82 percent sensitivity and 82 percent specificity with an area under the curve of 90 percent.

The company said all results from its algorithms were compared to measurements taken using the "gold standard" of in-laboratory poly-somnography scored using the current 2012 American Academy of Sleep Medicine scoring criteria.

Resapp's principal investigators Dr Philip Currie and Dr Ivan Ling said that "today's methods of sleep apnoea diagnosis, either sleep laboratory poly-somnography or home sleep testing, are not able to mass screen patients due to availability and costs, leaving a large unmet clinical and societal need to find a solution to population screen for [obstructive sleep apnoea], especially in patients with existing heart disease, obesity, hypertension, atrial fibrillation or type 2 diabetes".

Resapp chief executive officer Dr Tony Keating said that "by using an off the shelf smartphone, we have the opportunity to deliver a highly scalable, accurate and easy to use screening test for [obstructive sleep apnoea]".

"We now look forward to comparing the performance of our algorithms with home sleep testing, which is the final step before we make a regulatory submission," Dr Keating said.

Resapp fell one cent or 4.55 percent to 21 cents with 7.8 million shares traded.

ORTHOCELL

Orthocell says it has received $2,528,159 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Regeneus said the rebate related to research and development expenditure for the year to June 30, 2018.
Orthocell managing director Paul Anderson said the tax incentive “strengthens our balance sheet, supports our current Celgro market entry plans into key EU markets and enables progression of key [research and development] activities”.
Orthocell fell half a cent or two percent to 24.5 cents.

CARDIEX (FORMERLY ATCOR MEDICAL)

Cardiex says it has received a $1,500,000 subscription payment from C2 Ventures as part of its recent $5,000,000 capital raising.
Cardiex said that following shareholder approval the payment was made by chief executive officer Craig Cooper and director Niall Cairn’s Sydney-based company C2 Ventures and was paid a month ahead of the subscription date.
Cardiex fell 0.4 cents or 11.4 percent to 3.1 cents with 2.3 million shares traded.

ZELDA THERAPEUTICS

Zelda says it will cease its clinical trials in Chile with Fundación Daya to focus on its clinical trials in Australia and the US.
Zelda previously said it was conducting research in Chile that focused on autism, eczema and insomnia (BD: Sep 13, 2017).
Today, the company said it was conducting clinical trials in autism and insomnia in the US and Australia (BD: Apr 13, 2018; Nov 29, 2017).
Zelda managing director Dr Richard Hopkins said that “companies evaluating licence deals usually put greater weight on US and Australian-based clinical trials so it makes sense to focus on these markets”.
The company said it also had a pre-clinical research program to study the effects of cannabinoids on breast, brain and pancreatic cancer and to examine the potential for cannabinoids to treat diabetes-associated cognitive decline (BD: Apr 18, 2018).
Zelda fell 0.3 cents or 4.4 percent to 6.5 cents with 2.5 million shares traded.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICAL

MGC says the Australian Therapeutic Goods Administration has made Cannepil available through the authorized prescriber scheme for drug-resistant epilepsy.
MGC said that the TGA authorization followed Melbourne’s St Vincent’s Hospital “endorsement” of Cannepil for the treatment of adults with drug-resistant epilepsy.
MGC managing-director Roby Zomer said his company was “delighted to announce the availability of our first … Cannepil for supply under the Authorised Prescriber Scheme”.
“This is a significant achievement for us and we are very excited at the prospect of ramping up production to a commercial scale and bringing Cannepil to Australia,” Mr Zomer said.
The company said it would begin commercial scale production of Cannepil at its Slovenian facility and that the first batch of Cannepil was expected to be available for sale in Australia by December, 2018 and would be distributed by HL Pharma.
MGC climbed 1.6 cents or 31.4 percent to 6.7 cents with 97.2 million shares traded.

UNIVERSAL BIOSENSORS

CVC Limited says it has increased its substantial holding in Universal Biosensors from 16,651,964 shares (9.42%) to 21,944,614 shares (12.41%).
The Sydney-based CVC said that between October 2 and October 10 it purchased the 5,292,650 shares on-market for $1,180,529, or 22.31 cents a share.
Universal Biosensors was unchanged at 23 cents.

SIMAVITA

Simavita says that four substantial shareholders have been diluted, two have become substantial and two have been diluted below the five percent level.
Last week, Simavita said it raised $1,975,000 and today filed a notice on behalf of its substantial shareholders (BD: Oct 4, 2018).
Simavita said that Melbourne's Chevron Corp for the Peter Reilly Family Super Fund increased its holding from 35,511,650 CDIs (10.27%) to 52,178,317 CDIs (12.59%), the Dussman Group and directors Damien and Justin Haakman had their 102,019,031 CDI holding diluted from 29.49 percent to 24.62 percent; Jolimont Lodge for the Powell Family superannuation fund's 28,251,991 CDI holding was diluted from 8.17 percent to 6.82 percent; and the Hong-Kong-based WF Asian Reconnaissance Fund's 24,402,222 CDI holding was diluted from 8.45 percent to 5.89 percent; while George Tauber Management became substantial with 23,926,766 CDIs (5.77%) and Tiga Trading became substantial with 48,212,657 CDIs (11.63%).
The company said that Daniel Hegglin and the Robert Hutchinson and Mary Ann McKenzie Superannuation Fund were no longer substantial shareholders.
Simavita was untraded at 3.1 cents.

SUDA PHARMACEUTICALS

Suda says it has appointed Andrew Curtis as head of business development and alliance management in the US, effective from October 15, 2018.
Suda said Mr Curtis was previously the US chief executive officer of the Heidelberg, Germany-based Affimed and led Pfizer's establishment of a rare disease business unit.
Suda was up 0.5 cents or 12.5 percent to 0.45 cents with 5.6 million shares traded.

CLARITY PHARMACEUTICALS

Clarity says it has appointed Prof Jason Lewis to its scientific advisory board.
The Sydney-based Clarity said that Prof Lewis was currently New York's Memorial Sloan Kettering Cancer Center department of radiology research vice-chair as well as chief of Sloan Kettering's radiochemistry and imaging sciences service, and director of the Centre's radiochemistry and molecular imaging probe core facility.
The company said that Prof Lewis was also a professor at the Gerstner Sloan Kettering Graduate School of Biomedical Sciences and at Weill Cornell Medical College.
Clarity said that Prof Lewis held a Doctorate of Philosophy from the UK's University of Kent and had published more than 180 papers, books, book chapters and reviews.
Clarity is a public unlisted company.