Biotech Daily

Monday May 15, 2017

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: DIMERIX UP 17%, ONCOSIL DOWN 11.5%**

*** PHARMAXIS: '$41m BOEHRINGER INGELHEIM PXS-4728A MILESTONES'**

*** CYNATA REQUESTS PHASE I GvHD TRADING HALT**

*** MMJ STARTS MARIJUANA TRIAL FOR MS**

*** BARD1: 'LUNG CANCER TEST NEEDS MORE WORK'**

*** DORSAVI LAUNCHES SMALLER FASTER VIMOVE2, MYVIMOVE PROGRAM**

*** GLAXOSMITHKLINE $80k RESEARCH AWARD OPENS**

*** TDM TAKES 12% OF SOMNOMED**

MARKET REPORT

The Australian stock market edged up 0.03 percent on Monday May 15, 2017 with the ASX200 up 1.5 points to 5,838.4 points.

Eleven of the Biotech Daily Top 40 stocks were up, 20 fell, eight traded unchanged and one was untraded.

Dimerix was the best, up 0.1 cents or 16.7 percent to 0.7 cents, with 19,573 shares traded, followed by Pharmaxis up 11.5 percent to 29 cents with 1.7 million shares traded.

Bionomics and Prana climbed more than five percent; Clinuvel and Living Cell improved more than four percent; Psivida was up 3.8 percent; Actinogen and Avita rose more than two percent; Resmed and Viralytics were up one percent or more; with CSL and Medical Developments up by less than one percent.

Oncosil led the falls, down 1.5 cents or 11.5 percent to 11.5 cents with 1.2 million shares traded.

Compumedics lost 8.3 percent; Cellmid fell 6.9 percent; Cyclopharm and Mesoblast fell more than five percent; IDT, Impedimed and Opthea were down more than three percent; Benitec, Reva and Universal Biosensors shed more than two percent; Atcor, Cochlear, Factor Therapeutics, Nanosonics, Neuren and Sirtex were down more than one percent; with Airxpanders, Ellex, Pro Medicus and Starpharma down by less than one percent.

PHARMAXIS

Pharmaxis says it expects payments of EUR28 million ($A41.3 million) in milestone payments from Boehringer Ingelheim relating to PXS-4728A.

In 2015, Pharmaxis said the Ingelheim, Germany-based Boehringer Ingelheim International GmbH had an option on PXS4728A for non-alcoholic steato-hepatitis with other potential indications for PXS4728A including respiratory diseases such as chronic obstructive pulmonary disease (BD: Mar 12, 2015).

Today, Pharmaxis said that in addition to a phase II trial of PXS-4728A for non-alcoholic steato-hepatitis due to start mid-2017 which would earn a payment of EUR18 million, Boehringer had confirmed a phase II study for a second disease indication will commence this year, earning the company a further EUR10 million.

Pharmaxis chief executive officer Gary Phillips said that PXS-4728A was an anti-inflammatory drug “with excellent preclinical data in several disease models”.

“The structure of the deal with Boehringer anticipated its potential in more than one disease and the EUR10 million we expect for the second indication would bring total expected milestones received for starting phase II trials in two diseases to approximately $42 million in this calendar year,” Mr Phillips said.

“This is an important signal about Boehringer’s confidence in the potential of PXS-4728A to help patients,” Mr Phillips said.

“This significant injection of cash into the Pharmaxis business will allow us to strengthen our drug development pipeline in fibrosis and inflammation and add further scientific expertise,” Mr Phillips said.

“We aim to continue to build a company with the capability to translate and commercialise early stage research into assets with world class data sets that are highly valued by large [pharmaceutical] companies seeking partnerships,” Mr Phillips said.

Pharmaxis said that pending the successful development and commercialization of the PXS-4728A program, Boehringer Ingelheim would be due to pay up to EUR55 million in development milestone payments tied to the commencement of phase II and III trials in the first indication; up to EUR140 million in regulatory milestone payments on filing applications for marketing approval and receipt of regulatory and pricing approvals for a PXS-4728A product in the major pharmaceutical markets; additional milestone payments for a second indication, the same in aggregate for the first indication; earn-out payments on annual net sales of PXS-4728A program products; and commercialization milestone payments on specified levels of annual net sales of products.

The company said that Boehringer was responsible for all development, regulatory, manufacturing and commercialization activities.

Pharmaxis was up three cents or 11.5 percent to 29 cents with 1.7 million shares traded.

CYNATA THERAPEUTICS

Cynata has requested a trading halt “pending an announcement in relation to [its] phase I clinical trial”.

Last year, Cynata said the UK National Health Service Health Research Authority and the Royal Adelaide Hospital approved the 16-patient, phase I trial of its Cymerus mesenchymal stem cell product CYP-001 for steroid-resistant graft-versus-host disease (BD: Dec 13, 15, 2016).

Trading will resume on May 17, 2017 or on an earlier announcement.

Cynata last traded at 57 cents.

MMJ PHYTOTECH

MMJ says its Israeli subsidiary Phytotech Therapeutics will begin a 70-patients phase II trial of PTL201 cannabis capsules for multiple sclerosis spasticity.
MMJ said that safety and efficacy trial at Israel's Sheba Hospital would be a double-blind, randomized, placebo-controlled study to evaluate safety, tolerability and efficacy of oral PTL201 containing tetrahydrocannabinol and cannabidiol, with Sheba multiple sclerosis centre director Prof Anat Achiron as principal investigator.
The company said the efficacy endpoints would assess the change in spasticity numerical rate scoring, change in walking velocity and clinical global impression improvement, improvement of spasm frequency, sleep disturbance and decrease in pain.
MMJ said the phase II study would be undertaken simultaneously with the ongoing PTL101 paediatric epilepsy trial, and followed the phase I study which showed the safety and performance of the Gelpell-CBD oral capsule (BD: Feb 11, 16, 2016).
The company said that about 2.5 million had multiple sclerosis globally, with spasticity, involuntary muscle stiffness and spasms the most common and most debilitating symptoms affecting up to 84 percent of patients, with limited available treatments.
MMJ said the PTL201 drug beads contained tetrahydrocannabinol (THC) and cannabidiol (CBD) bound to gelatin matrix beadlets in gastro-resistant capsules.
MMJ was unchanged at 38 cents with 1.7 million shares traded.

BARD1 LIFE SCIENCES

Bard1 says it needs to do further work to improve the accuracy of its lung cancer test.
Bard1 said that a 638-sample lung cancer study had a receiver operating characteristic area-under-the-curve for accuracy of 0.82 in the training sets for calibrating the lung cancer test and 0.725 in the test sets, or 72.5 percent accuracy.
The company said the research study was conducted at the Rockville, Maryland-based Meso Scale Diagnostics using Meso's research-use only instrument platform to detect lung cancer in 638 retrospectively collected samples, across a broad range of lung cancer subtypes and stages.
Bard1 said the study aimed to refine both the multi-analyte Bard1 panel and algorithm for the early detection of lung cancer and to establish the performance characteristics using the Meso platform across different cancer stages and common histological subtypes.
The company said that the training sets used to develop the model had a receiver operating characteristic (ROC) - area under the curve (AUC) of 0.82, whereas the test sets used to validate the model achieved a lower AUC of 0.725.
Bard1said it had identified a combination of technical factors, including changes to the assay and patient cohort that might have contributed to reduced performance.
The company said it was working with scientists, clinical experts and industry leaders to resolve the issues and planned to optimize the assay and validate the analytical performance of the test, before further clinical validation.
The company said the planned clinical validation studies for the lung cancer test would be delayed until completion of the assay development phase and analytical validation.
Bard1 said the same product development and analytical validation steps would apply to its research-grade ovarian cancer test, before starting future clinical validation studies.
In March, Bard1 said that in a clinical trial of its ovarian cancer on 348 samples of which 200 were from women with ovarian cancer and 148 were controls, the test had 87 percent specificity and 90 percent sensitivity, with an overall receiver operating characteristic area-under-the-curve for accuracy of 0.92 (BD: Mar 23, 2017).
Bard1 fell 1.9 cents or 52.8 percent to 1.7 cents with 24.7 million shares traded.

DORSAVI

Dorsavi says it has launched Vimove2 with “smaller, faster and easier to use sensors” and the patient mobile telephone application Myvimove.

Dorsavi said that Vimove2 had “a simplified software interface, improved reporting tools, out of clinic monitoring, comprehensive exercise video library” and the Myvimove application which could deliver assessment reports, customized exercise programs and data collection for out-of-clinic monitoring, designed to engage patients in their treatments.

The company said that Vimove2 movement sensors were about one third the size of the original Vimove sensors and were “easy and quick to use for time-conscious clinicians”.

Dorsavi said that Vimove2 came in three modules of low back, knee and run with further modules to be released over the next 12 months.

The company said the Vimove2 had a substantially reduced cost of goods and a lower entry sale price, allowing it to build a critical mass of devices in market.

Dorsavi said the Vimove2 had been developed as an on-going annuity revenue product, replacing the model of outright unit sale or short-term lease originally launched for Vimove.

The company said that the annuity model had been tested in the US over the past 12 months and had been successful in facilitating sales and providing a steady revenue stream.

Dorsavi said that following the Australian Vimove2 launch, focussed on building clinical adoption with physiotherapists, chiropractors, osteopaths and exercise physiologists, it would target the UK and the US.

Dorsavi chief executive officer Dr Andrew Ronchi said the new product “brings together new technology and significant insights from the clinical market”.

“Vimove2 is highly intuitive, simple and a faster-to-use device with the addition of a patient [application], allowing patients and therapists to continue to monitor progress and improve adherence to treatment regimes,” Dr Ronchi said.

Dorsavi was up two cents or 6.45 percent to 33 cents.

GLAXOSMITHKLINE

Glaxosmithkline says its $80,000 Award for Research Excellence has opened for nominations, which will close on July 10, 2017.

Glaxosmithkline said it was the 37th year of the Award for Research Excellence and had been awarded since 1980 “to recognize outstanding achievements in medical research with potential importance to human health”.

The company said that last year’s award went to Prof Arthur Christopoulos and Prof Patrick Sexton for their research into G-protein-coupled receptors.

Glaxosmithkline Australia medical director Dr Andrew Weekes said the award was “a flagship programme for GSK Australia and a highlight in our calendar each year”.

“Ground-breaking medical research is only possible if a range of industry, academia, professional bodies and Government work together,” Dr Weekes said.

“If Australia is to remain a world leader in medical research then it’s important we all get behind our local researchers and scientists,” Dr Weekes said.

Glaxosmithkline said that successful applicants were generally mid-career researchers with a long-standing commitment to their field and the winner would be announced on October 12, 2017 at the Research Australia awards in Melbourne.

More information is at the Glaxosmithkline Award for Research Excellence website http://au.gsk.com/en-au/research/gsk-award-for-research-excellence/, where nominees could be submitted. Email enquires to: are.arenominations@gsk.com.

SOMNOMED

TDM Asset Management says it has increased its holding in Somnomed from 6,247,419 shares (10.88%) to 6,917,454 shares (11.95%).

The New York-based TDM said it exercised 400,000 options at $3.00 each and bought 270,035 shares at market prices.

The TDM substantial shareholder notice was signed by company secretary Jason Sandler and said that associated entities included TDMAM Pty Ltd, Madleowill Investments Pty Ltd, Zoolander Investments Pty Ltd, Thomas Cowan, Rebecca Cowan, Hamish Corlett and Benjamin Gisz.

Somnomed fell four cents or 1.3 percent to $3.10.