Biotech Daily

Thursday September 18, 2014

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: COMPUMEDICS UP 12%, ACRUX DOWN 26%**

*** ACRUX FALLS AS MUCH AS 31% ON FDA TESTOSTERONE MEETING**

*** OSPREY LAUNCHES AVERT PLUS 'SMART' SYRINGE MONITOR SYSTEM**

*** CYNATA LICENCES STEM CELLS FROM CELLULAR DYNAMICS**

*** GI DYNAMICS: 'ENDOBARRIER REDUCES HEART RISK'**

*** STARPHARMA REQUESTS CAPITAL RAISING TRADING HALT**

*** SUDA WINS ISO 9001:2008 CERTIFICATION**

*** RHINOMED APPOINTS TRISPORTS JAPAN TURBINE DISTRIBUTOR**

*** BIOXYNE APPOINTS IAN BROWN PROBIOTICS CONSULTANT**

*** MARK PEATEY REPLACES ITL DIRECTOR SANJAY SEHGAL**

MARKET REPORT

The Australian stock market rose 0.16 percent on Thursday September 18, 2014 with the S&P ASX 200 up 8.5 points to 5,415.8 points. Nine of the Biotech Daily Top 40 stocks were up, 14 fell, 14 traded unchanged and three were untraded. All three Big Caps rose.

Compumedics was the best, up 1.5 cents or 12 percent to 14 cents with 380,821 shares traded.

Clinuvel, Prima and Psivida climbed five percent or more; Ellex and Genetic Technologies rose more than four percent; Admedus and Phosphagenics were up more than three percent; Circadian rose 2.8 percent; with Cochlear, CSL and Resmed up by less than one percent.

Acrux led the falls, closing down 44 cents or 26.0 percent at $1.25 with 8.5 million shares traded.

Cellmid fell 7.1 percent, Avita and Bionomics were down more than six percent; Analytica was down 5.3 percent; Benitec fell 4.2 percent; Impedimed, Living Cell, Nanosonics and Tissue Therapies were down three percent or more; with GI Dynamics, Mesoblast, Neuren and Sirtex down by less than one percent.

ACRUX

Acrux's share price tumbled as much as 31.1 percent following a US Food and Drug Administration Advisory Committee meeting on testosterone replacement therapy (TRT).

Unconfirmed reports said the joint meeting of the Bone, Reproductive And Urologic Drugs Advisory Committee and the Drug Safety And Risk Management Advisory Committee voted overwhelmingly on two questions relating to testosterone replacement therapy.

The joint Committee found no evidence for increased cardiovascular events related to testosterone replacement therapy but recommended more research.

Acrux has licenced its Axiron testosterone replacement therapy to the US-based Eli Lilly and told the ASX that the FDA panel "concluded that there is insufficient evidence that testosterone use leads to an increased risk of cardiovascular events".

The company said that the panel recognized that there were no large studies available that were designed to specifically address the question and recommended that companies be required to conduct additional studies to assess the cardiovascular risk of their products for patients with age-related low testosterone.

Acrux said that the results of several studies were expected in the next six months, including a Lilly study and three studies funded by the US National Institutes of Health.

The company said the Lilly study would evaluate the impact of testosterone on energy level and sexual arousal, interest and drive, as well as the safety of testosterone and although not designed to assess the risk of cardiovascular events, the study would collect information on cardiovascular events, with the last patient visit scheduled for October 2014.

Acrux said that the FDA asked the advisory panel to consider the current indication for testosterone therapies and the panel voted in favor of changing language in the products' labels to restrict the intended uses of the drugs, particularly in relation to age-related low testosterone.

The company said that according to the FDA, 21 percent of patients prescribed testosterone did not appear to have their testosterone concentrations tested before or during treatment and Lilly encouraged physicians to check testosterone levels during therapy and to monitor treatment, consistent with the Axiron product label.

Acrux said that the FDA was not obliged to follow the advice of its advisory panels and it was "premature to speculate how the FDA will consider the Committee's recommendation today and whether the prescribing physicians will change their prescribing habits if any labelling changes are required by the FDA".

The FDA published background documents for the two major issues, the appropriate indicated population and the potential for adverse cardiovascular outcomes.

An epidemiology report from the Office of Surveillance and Epidemiology Review to the Advisory Committee said that "based on the review of the meta-analysis of [randomized controlled trials] and the five observational studies, the evidence for increased risk of cardiovascular events with TRT [testosterone replacement therapy] is not conclusive".

"These observational studies do not provide convincing evidence for the benefit or risk associated with TRT due to the study limitations outlined; they do provide some information regarding the patient characteristics in the treated and untreated patient populations," the report said.

A research note from Macquarie Equities published before the market opened today said that the panel voted 20 to one to restrict the use of testosterone replacement therapy and to further assess safety, and valued the company as an "underperform" at 56 cents with a 12 month price target of 65 cents.

Acrux fell as much as 52.5 cents or 31.1 percent to $1.165, before closing down 44 cents or 26.0 percent at $1.25 with 8.5 million shares traded.

OSPREY MEDICAL

Osprey has launched its Avert Plus combination of the Avert dye reduction system, combined with a ‘smart’ syringe and comprehensive monitor.

Osprey chief executive officer Mike McCormick told a teleconference today that the Avert Plus was launched at the Transcatheter Cardiovascular Therapeutics meeting in Washington DC, from September 12 to 17, 2014.

Mr McCormick said that the combination of the Avert cardiac dye reductions system with the controlled and monitored Cintrack syringe system received Conformité Européenne (CE) mark approval in August and a 510k pre-market approval application was submitted to the US Food and Drug Administration (FDA) on August 1, 2014.

Mr McCormick said he was hopeful of FDA approval in November or December this year.

Mr McCormick said that contrast-induced nephropathy was a potentially life-threatening result of the injection of dye, typically used when inserting a stent into coronary arteries.

He said that the Avert system captured unused dye reducing the risk for patients with compromised kidneys.

Mr McCormick said that the mechanically controlled syringe and touch screen liquid crystal display monitor provided more accurate accounts of dosages administered, improving patient care and reducing costs.

Mr McCormick said that changes legislated under President Barack Obama’s Affordable Health Care Act were “driving new performance standards to improve outcomes and reduce costs”.

He said that records were required “and our system does that”.

Mr McCormick said that the Avert Plus system could monitor real-time volume threshold monitoring, provide accurate contrast dye dosage and display the amount of contrast dye diverted by the Avert system.

Mr McCormick said that the original Avert system was priced at $US350 to $US400 and the Avert Plus would cost about $US450 per unit.

He said that a 700-patient clinical trial comparing 350 patients using the Avert system to 350 standard-of-care patients had recruited more than 100 patients and was expected to be fully recruited by mid-2015.

Osprey was unchanged at 62 cents.

CYNATA THERAPEUTICS

Cynata says it has licenced a clinical grade human induced pluripotent stem cell line from the Madison, Wisconsin-based Cellular Dynamics International.

Cynata said that the stem cell line would be used as high quality starting material to manufacture its Cymerus mesenchymal stem cell products for human therapeutic use.

The company said that its Cymerus technology enabled the scalable manufacture of mesenchymal stem cells for therapeutic use.

Cynata chief executive officer Dr Ross Macdonald said that the agreement “paves a clear path for commercialization of our Cymerus technology through access to an [induced pluripotent stem cell line] starting material”.

“Our technology transfer, up-scaled manufacture process development and pre-clinical activities thus far have proceeded very well and according to plan using [induced pluripotent stem cell] starting materials suitable for this phase,” Dr Macdonald said.

Dr Macdonald said that Cellular Dynamics founders were Dr James Thomson and Prof Igor Slukvin, who were also co-inventors of the Cynata technology.

Cynata was up five cents or 12.5 percent to 45 cents.

GI DYNAMICS

GI Dynamics says that a pooled analysis of 40 patients shows that its Endobarrier duodenal sleeve improves body weight, glycaemic control and cardiovascular risk.

GI Dynamics said that the new data demonstrated "clinically meaningful improvements in the prevalence of metabolic syndrome, as well as a reduction in 10-year cardiovascular risk in obese patients treated with Endobarrier therapy".

The company said that the San Antonio-based University of Texas Health Science Center cardiology professor Prof Robert Chilton presented the findings in a poster presentation at the European Association for the Study of Diabetes meeting in Vienna, Austria.

"The findings from our pooled analysis demonstrated that Endobarrier therapy for obese patients with and without diabetes, resulted in significant improvements in body weight, glycaemic control and multiple cardio-metabolic risk factors, which translated to a consistent reduction in the patients' 10-year estimated [cardiovascular] risk," Prof Chilton said. "While further exploration is warranted, Endobarrier therapy appears to be an effective tool to rapidly improve a patient's cardio-metabolic health, offering clinicians an adjunctive approach to currently available pharmacotherapy and an alternative to existing surgical options."

GI Dynamics said that the findings were from two clinical studies of Endobarrier involving a total of 40 obese patients with and without type 2 diabetes who completed 12 months of treatment with Endobarrier therapy.

The company said that the results showed that during treatment, the overall cohort lost an average of 18.6 percent in total body weight and 17.7cm from the waist measurement.

GI Dynamics said that systolic blood pressure dropped by 7.6mmHg, low density lipoprotein cholesterol decreased by 0.6mmol/L, and HbA1c levels were reduced by an average of 2.1 percent in the 20-patient diabetic subgroup.

The company said that given these improvements, the number of patients who met the criteria for metabolic syndrome at the time of Endobarrier implant was reduced by 37 percent from 35 patients to 20 patients.

GI Dynamics said that Endobarrier therapy resulted in a 19 to 40 percent reduction in 10-year cardiovascular risk level, as calculated by three different risk models.

The company said that four other scientific posters were presented at the meeting demonstrating that implantation of the Endobarrier device in morbidly obese patients with and without type 2 diabetes resulted in increased circulating bile acids, similar to the increase observed in gastric bypass procedures.

GI Dynamics said that the findings might provide a hypothesis for the Endobarrier's potential mechanism of action.

GI Dynamics chief medical officer Dr David Maggs said that "type 2 diabetes and obesity pose a growing challenge in clinical practice, and we believe Endobarrier therapy represents an important advancement in addressing these dual epidemics".

"The body of evidence supporting the use of Endobarrier therapy continues to grow, not only for its ability to improve type 2 diabetes and obesity, but also for its impact on overall cardio-metabolic health," Dr Maggs said.

GI Dynamics fell half a cent or one percent to 48 cents.

STARPHARMA

Starpharma has requested a trading halt "pending an announcement to the market regarding the completion of an equity capital raising".

Trading will resume on September 22, 2014 or on an earlier announcement.

Starpharma last traded at 71 cents.

SUDA

Suda says it has been awarded ISO 9001:2008 certification for its quality management system by the certification authority, Bureau Veritas Australia.
Suda said that the ISO 9001:2008 international standard verified that its quality management system met the requirements of documentation required by the pharmaceutical industry, statutory authorities and regulators and ensured that its in-house activities and projects undertaken with pharmaceutical partners generated consistent and good quality data.
Suda chief executive officer Stephen Carter said the certification was “an important step to establish Suda as a high quality organization and the partner-of-choice for formulating drugs into oral sprays”.
Suda was unchanged at 5.4 cents with 1.4 million shares traded.

RHINOMED

Rhinomed says it has appointed the Kobe, Japan-based sporting goods wholesaler Trisports to distribute its Breatheassist Turbine range of nasal plugs in Japan.
Rhinomed said that Trisports would distribute the products to the cycling, triathlon and sporting goods retail sector.
Rhinomed fell 0.1 cents or 2.8 percent to 3.5 cents.

BIOXYNE

Bioxyne says it has appointed Ian Brown as a strategic marketing consultant to review the company’s core probiotics business.
Bioxyne said that Mr Brown would review the positioning of the lactobacillus strain of probiotics to widen product offerings and distribution.
The company said that Mr Brown held a Masters of Business Administration from the University of Queensland and was previously the chief executive officer of the UK-based Repregen and prior to that was the chief operating officer and executive director of Cordlife.
In 2011, Hunter Immunology merged with Probiomics to become Bioxyne and develop HI-164OV for chronic obstructive pulmonary disease, but the 320-patient trial failed to meet its primary endpoint (BD: Oct 11, 2011; Jun 28, 2012).
Bioxyne was up 0.1 cents or 5.3 percent to two cents.

ITL

ITL says Mark Peatey has been appointed as an independent non-executive director effective from October 1, 2014, replacing Sanjay Sehgal.
ITL said that Mr Peatey had experience in corporate advisory services and previously worked for IBM in the UK and later at Ernst & Young, before becoming a founding partner of Maxim Chartered Accountants.
The company said that Mr Sehgal had relocated to the US and decided he would not stand for re-election at the annual general meeting and would retire on October 31, 2014.
ITL was untraded at 21 cents.