Biotech Daily

Wednesday February 5, 2014

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: REVA UP 10%, CIRCADIAN DOWN 11%**

*** ACRUX TELLS ASX: 'REPORT CUT PRICE 10%', $US50m 2015 MILESTONE**

*** US PATENT FOR VIRALYTICS CAVATAK**

*** LANCET PAPER BACKS SPINIFEX EMA401 FOR NEURALGIA**

*** ALL CHANGE AT ISONEA, POKIES BRUCE MATHIESON ABOARD**

*** HANRINE, GINA RINEHART INVEST $1.4m IN ORIL, TAKE 27%**

*** PERPETUAL REDUCES TO 11% OF SIRTEX**

*** HEALTHLINX COMPLETES 500-FOR-1 CONSOLIDATION**

MARKET REPORT

The Australian stock market fell 0.53 percent on Wednesday February 5, 2014 with the S&P ASX 200 down 26.8 points to 5,070.3 points.

Twelve of the Biotech Daily Top 40 stocks were up, 17 fell, nine traded unchanged and two were untraded.

Reva was the best, up four cents or 9.8 percent to 45 cents with 62,500 shares traded.

Benitec climbed 7.7 percent; Clinuvel was up 5.2 percent; Viralytics was up 4.4 percent; Admedus, Atcor, Cellmid, Prana and Tissue Therapies were up more than three percent; Neuren rose 2.1 percent; Bionomics, Cochlear and Resmed were up more than one percent; with Medical Developments up 0.4 percent.

Circadian led the falls, down 2.5 cents or 10.6 percent to 21 cents with 3,000 shares traded.

Genetic Technologies and Universal Biosensors lost more than eight percent; Acrux and Pharmaxis fell more than seven percent; QRX was down 6.2 percent; GI Dynamics, Mesoblast and Psivida were down more than five percent; Nanosonics and Prima fell more than four percent; Ellex lost 3.45 percent; Osprey and Starpharma shed more than two percent; Alchemia, CSL and Optiscan were down more than one percent; with Sirtex down 0.9 percent.

ACRUX

Acrux has told the ASX that “a report” relating to an US Food and Drug Administration inquiry into cardiac impacts of testosterone caused a share price fall.

The ASX said the company’s share price fell 9.9 percent from $2.32 on February 3 to $2.09 on February 4, 2013 and noted an increase in trading volume.

Yesterday, Acrux fell as much as 26 cents or 11.2 percent to $2.06 before calling a halt to respond to the ASX, down 24 cents or 10.3 percent at $2.08 with 2.85 million shares traded (BD: Feb 4, 2014).

On January 31, 2014 in the US, the FDA said it was investigating cardio-vascular risks in men taking approved testosterone products and it would reassess the safety issue based on the publication of two studies that suggested an increased risk of cardiovascular events among groups of men prescribed testosterone therapy” (BD: Feb 4, 2014).

The FDA referred to an observational study published in November 2013 which suggested that older men had a 30 percent increased risk of stroke, heart attack and death in the group prescribed testosterone therapy; and a second study published on January 29, 2014 that reported an increased risk of heart attack in older men, as well as in younger men with pre-existing heart disease, but not younger men without a heart disease history.

Today, Acrux said: “A report was publicised, and circulated on February 4, 2014, which misrepresented the articles conclusions and the FDA DSC, and Acrux believes that this triggered the recent trading in its securities.”

The FDA announcement was reported in the US-based Fiercepharma on January 31, 2014, an ‘underperform’ research note was published by Macquarie Private Wealth, yesterday, with a $1.80 valuation and target price, Wilson HTM analyst Dr Shane Storey published a report that Acrux was a ‘hold’ and worth $3.70, Biotech Daily published a News Flash on the share price fall yesterday and Morgans analyst Scott Power released a report this morning and told Biotech Daily he retained a target price of $2.70.

Separately, Acrux said that it expected to be paid a $US50 million milestone by Eli Lilly in 2015 based on increasing sales of Axiron, but did not specify the level, which Biotech Daily believes to be more than $US200 million in sales in one year.

Acrux fell 16.5 cents or 7.9 percent to $191.5 with 5.8 million shares traded.

VIRALYTICS

Viralytics says the US Patent and Trademark Office has allowed a patent relating to treating malignancies using its lead product Cavatak.

Viralytics chief scientific officer Dr Darren Shafren told Biotech Daily that the patent was entitled ‘Methods for treating malignancies using Coxsackieviruses and it would expire in mid-2021

Viralytics said that Cavatak (Coxsackievirus A21) was protected with a portfolio of patents across major world markets, including in the US for a number of Group A Coxsackie viruses including Cavatak.

The company said that the additional US patent broadened patent protection across all Coxsackie A viruses and the much wider group-C human enteroviruses that attach to intercellular adhesion molecule-1 (ICAM-1) in the process of targeting and destroying cancer cells.

Viralytics chief executive officer Dr Malcolm McColl said the US patent would “significantly expand Viralytics’ intellectual property portfolio in the US to cover the broad use of all group-C human enteroviruses, including Cavatak, that target and destroy cancerous cells following binding to cell surface expressed ICAM-1”.

Viralytics was up 1.5 cents or 4.4 percent to 35.5 cents.

SPINIFEX PHARMACEUTICALS

Spinifex says a paper on its 183-patient, phase II trial showing that EMA401 reduces pain in post-herpetic neuralgia compared to placebo has been published in the Lancet.

The article, entitled 'EMA401, an orally administered highly selective angiotensin II type 2 receptor antagonist, as a novel treatment for post-herpetic neuralgia: a randomised, double-blind, placebo-controlled phase II clinical trial', provided detail on the results first published in 2012 in which EMA401 met its primary endpoint, reduction in mean daily pain score versus placebo over the last week of 28 days of treatment an abstract is at: http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(13)62337-5/abstract.

Spinifex said in 2012 that the results showed a statistically significant and clinically meaningful reduction in mean pain intensity from baseline to week four for subjects on active treatment when compared to placebo. (BD: Aug 28, 2012).

Today, the Lancet article said that EMA401 (100mg, twice daily) provided "superior relief of post-herpetic neuralgia compared with placebo … [and] was well tolerated by patients".

Spinifex said that EMA401 was a novel angiotensin II type 2 (AT2) receptor antagonist under development as a potential first-in-class oral treatment for chronic pain without central nervous system side effects.

Spinifex said that post-herpetic neuralgia was a painful condition following herpes zoster or shingles and existing therapy did not relieve pain for all individuals.

The Lancet article said the mean pain intensity reduction from baseline after four weeks treatment was -2.29 in the EMA401 group and -1.60 in the placebo group ($p = 0.007$).

Spinifex said that a significantly greater proportion of patients on active treatment reported a more than 30 percent reduction in mean pain intensity score compared to baseline with 57.6 percent for EMA401 and 35.2 percent for placebo ($p = 0.0023$), meeting a key secondary endpoint.

The company said that a subgroup of patients who had moderate or severe pain at study entry continued to take a single existing medicine for their post-herpetic neuralgia during the study and patients randomized to EMA401 achieved significantly greater pain reduction when compared to patients on placebo.

Spinifex said that pain relief was also observed in those patients that were not taking a single existing medicine, indicating that EMA401 might have the potential to provide relief for patients who don't achieve optimal pain relief with current treatments or who don't wish to continue with these medicines due to their side effects.

The company said that EMA401 was generally safe and well tolerated with no serious treatment related adverse events reported.

Spinifex said that in a commentary also published in the Lancet, Denmark's Aarhus University researcher Dr Nanna Finnerup described this first clinical study to evaluate the efficacy of an AT2 receptor antagonist in neuropathic pain as encouraging.

"Most importantly, their work identifies a possible new drug for the treatment of neuropathic pain with a novel mechanism of action, and thus offers hope for patients who have insufficient pain relief with presently available drugs," Dr Finnerup said

Lead author of the Lancet article Imperial College London's Prof Andrew Rice said the results "demonstrated EMA401 was able to significantly reduce pain in patients with post-herpetic neuralgia and was well tolerated."

"This paper is the first publication of the clinical effects of any AT2 receptor antagonist and contributes to our understanding of the potentially important role of this new drug class in relieving chronic pain," Prof Rice said. "These results are an exciting step in the development of a novel approach to the treatment of neuropathic pain and chronic pain more generally."

Spinifex is a private company.

ISONEA

Isonea has replaced its board and management, appointing Leon L'Huillier as chairman with Bruce Mathieson and John Ribot-de-Bresac as directors.

Last year, Isonea said chief executive officer Michael Thomas would depart from the company in 2014 (BD: Nov 13, 2013).

Last month, Isonea said that chairman Dr Stewart Washer had resigned with Ross Haghighat promoted to chairman, director Jerry Korten appointed chief executive officer and Dr Tim Oldham appointed as a director (BD: Jan 19, 2014).

Today, Isonea said that Dr Oldham remained but Mr Haghighat, Mr Korten and directors Dr Ross Macdonald and David Dantzker would leave the company.

Isonea said that the head of operations Stephen Tunnell had been promoted to managing director and appointed to the board.

Isonea said that Mr L'Huillier was a former director of Woolworths and was currently a deputy chairman of Australian Prostate Cancer Research, a former chairman of the Australian Health Ministers Advisory Council, The Royal Children's Hospital Brisbane and a former director of Melbourne's St Vincent's Hospital and The Bernard O'Brien Institute of Microsurgery.

The company said that Mr L'Huillier was previously a director of private equity in association with Archer Capital, Gresham, and Macquarie Bank.

Isonea said that Mr Mathieson was currently a director of Mayne Pharma and Western Desert Resources, a current director and former chief executive officer of gambling machine company Australian Leisure and Hospitality Group, owns about 325 hotels and 520 retail outlets across Australia and employs more than 15,000 staff.

The company said that Mr Mathieson "trained as an engineer and brings management and transactional experience across a number of industries to the board".

Isonea said that Mr Ribot-de-Bresac had "distinguished sports career" and was instrumental in the establishment of the Brisbane Broncos and Melbourne Storm rugby league clubs and as chairman of the Brisbane Roar soccer club.

The company said that Mr Ribot-de-Bresac was currently a director of Victorian Major Events Company, executive chairman of Queensland Clubs Management and owned "hospitality venues" throughout Queensland.

Isonea said that Dr Oldham was previously in senior management at Hospira and Mayne Pharma and was currently a director of Acrux.

The company said that Mr Tunnell was a sales and marketing executive specializing in respiratory medicine, professional fitness and mobile health and was formerly with Puritan Bennett.

Isonea said the immediate priorities for the board in 2014 would be to refine the product, progress US Food and Drug Administration approval and validate marketability to physicians, pharmacists and patients as part of our commercialization strategy.

Originally called Karmelsonix, in 2006 the company was formed through an alliance of respiratory technologies from the Pulmosonix division of Premier Bionics and the Israel based Karmel Medical Acoustic Technologies to develop and market five different machines for respiratory illness diagnosis and management (BD: Nov 24, 2006).

The company was established with Peregrine Corporate's Peter Marks as chairman, with Dr Henry Pinskier and inventor Dr Noam Gavriely as directors.

In 2011, Karmelsonix changed its name to Isonea with Ross Haghighat becoming substantial through Triton Systems (BD: Aug 30, Sep 7, 2011).

In September 2013, Investment Holdings, an entity owned by gambling machine operator Bruce Mathieson held 48,000,000 shares or 18.59 percent (BD: Sep 23, 2013).

Isonea was up 1.5 cents or 4.7 percent to 33.5 cents.

ONCOLOGY RESEARCH INTERNATIONAL LIMITED

Oncology Research International Limited (Oril) says that mining magnate Gina Rinehart's Hanrine Investments has increased its holding with a $1.4 million investment.
Oril said its shareholders approved the investment at a general meeting in Perth and Hanrine, a wholly-owned subsidiary of Hancock Prospecting held 27.23 percent of the company.
Oril said the funds would allow it to complete its preclinical and clinical program to a phase I trial, scheduled for completion by 2015.
The company said its ORIL007 lead oncology compound was originally isolated from a range of commonly found plants in trace amounts.
Oril said it had designed a novel synthetic route and manufactured commercial quantities of ORIL007, which was in late preclinical testing with plans to complete a phase I trial for safety, tolerability and indicative clinical efficacy in multiple cancer types by 2015.
The company said that the plant-based compounds targeted cancer cell membranes causing apoptosis or programmed cell death, without damaging health cells.
Oril said the compounds had a first-in-class mode of action, which worked across a wide range of cancer types.
In January, Oril chief executive officer Dr Philip Marshall told Biotech Daily that the mechanism of action in achieving apoptosis would be described when the appropriate patents had been approved.
Today, the company said it had raised $9.2 million through equity investment over the past three years to fund its novel oncology program.
Dr Marshall said the company was "delighted with Hanrine's increased investment, which represents a significant endorsement of ORIL's technology platform and future".
Oril is a public unlisted company.

SIRTEX MEDICAL

Perpetual and its subsidiaries have reduced their substantial shareholding in Sirtex from 6,979,295 shares (12.44%) to 6,387,618 shares (11.38%).
Perpetual said it bought and sold shares between October 30, 2013 and February 3, 2014 for prices ranging from $11.05 to $14.12.
Sirtex fell 13 cents or 0.9 percent to $13.97 with 369,545 shares traded.

HEALTHLINX

Healthlinx says it has completed its 500-for-one share consolidation and the company has 25,239,830 shares on issue.
Healthlinx said new holding statements had been sent to shareholders.
Healthlinx was in a suspension.