Biotech Daily

Friday January 29, 2016

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: BIOTRON UP 18%, IMPEDIMED DOWN 6%**

*** PHOSPHAGENICS TPM-OXYCODONE FOR PAIN 'NON-SIGNIFICANT'**

*** VICTORIA APPOINTS $60m INNOVATION BOARD, LITTLE BIOTECH INPUT**

*** CYCLOPHARM: 'TECHNEGAS CAN DIAGNOSE COPD'**

*** ACRUX, ELI LILLY AXIRON 2015 SALES DOWN 9% TO $218m**

*** ELLEX H1 SALES REVENUE UP 13% TO $35m**

*** NANOSONICS $16m RECORD H1 SALES REVENUE**

*** ANALYTICA SIGNS TWO MORE UK PERICOACH DISTRIBUTORS**

*** HEARTWARE ENDS VALTECH TAKE-OVER, ENGAGED TAKES SEAT**

*** BIOTECH DAILY APPENDIX 4C QUARTERLY REPORTS POLICY**

*** PHARMAUST ONE QUARTER CASH; $560k RECEIVED, $550k COMING**

*** MEDICAL AUSTRALIA LESS THAN SIX MONTHS CASH, VET DIVESTED**

*** 3D MEDICAL APPOINTS JENNI PILCHER CEO, CFO**

MARKET REPORT

The Australian stock market was up 0.59 percent on Friday January 29, 2016 with the ASX200 up 29.3 points to 5,005.5 points. Sixteen of the Biotech Daily Top 40 stocks were up, 17 fell, six traded unchanged and one was untraded. All three Big Caps fell.

Biotron was the best on no news, up 0.9 cents or 17.7 percent to six cents with 424,605 shares traded. Nanosonics climbed 9.4 percent; Osprey was up 7.1 percent; Ellex and Viralytics rose more than four percent; Benitec and Compumedics were up more than three percent; Atcor, IDT, Reva and Universal Biosensors were up more than two percent; Anteo, Clinuvel and Medical Developments were up more than one percent; with Pro Medicus and Starpharma up by less than one percent.

Impedimed led the falls, down seven cents or 6.2 percent to $1.06 with 375,430 shares traded. Living Cell lost six percent; Cellmid, Genetic Technologies and Optiscan fell four percent or more; Actinogen, Bionomics and Mesoblast were down three percent or more; Acrux, Cochlear, CSL, Orthocell, Prana, Prima and Uscom shed more than two percent; with Admedus, Antisense, Polynovo, Resmed and Sirtex down by more than one percent.

PHOSPHAGENICS

Phosphagenics says that its TPM-oxycodone patch failed to reduce pain more than placebo in its 28-patient, phase IIa, proof-of-concept trial for post-herpetic neuralgia pain.

Phosphagenics said that the TPM-oxycodone patch did not meet the endpoint of demonstrating that locally delivered oxycodone could significantly ($p < 0.05$) reduce pain scores compared to placebo.

Phosphagenics initially said it was developing the TPM technology to deliver insulin and replace injections, before moving to deliver a range of other drugs including diclofenac, marketed as Voltaren (BD: Feb 24, Sep 10, 2009).

In 2009, Phosphagenics claimed phase I success for TPM-retinoic acid (vitamin A) for acne but a 53-patient phase II trial showed no significant difference between tretinoin and TPM-tretinoin gel for acne vulgaris (BD: Apr 30, 2009; Oct 7, 2014).

Today, Phosphagenics said that the mean reduction from baseline in average pain scores was minus 0.39 (+/- 0.347) for the TPM-oxycodone patch and minus 0.53 (+/- 0.353) for the vehicle control.

The company said that the randomized, double-blind, vehicle-controlled, crossover study trial achieved “key pharmacokinetic, performance and safety objectives including demonstrating that the TPM-oxycodone patch could “deliver drug to the targeted site in the skin while maintaining sub-therapeutic blood levels and maintaining a safety and side effect profile in line with that of placebo”.

The company said the positive findings supported partnering discussions and the applicability of the patch for other pain indications.

Phosphagenics said that each patient received a three-day treatment with both the TPM-oxycodone patch and the equivalent TPM-vehicle control patch, separated by a washout period of 10 days.

The company said that patch performed well in the older patient population, maintaining the oxycodone delivery profile established in prior phase I clinical studies on healthy volunteers, with good three-day adhesion characteristics in line with expectations for a commercial patch, excellent skin tolerability, with minimal dermal irritation, good drug delivery with minimal, or sub-therapeutic, systemic exposure to avoid opioid side effects and an attractive side effect profile similar to the placebo/vehicle patch, without evidence of opioid side effects associated with oral dosage forms, such as nausea, constipation or sedation.

The company said that post-herpetic neuralgia was “a complex and problematic disease to treat and recent population studies … have shown that specific patient sub-groups can display different pain patterns and different responses to common therapies”.

Phosphagenics chief executive officer Dr Ross Murdoch said the trial was designed to answer whether the patch performed as designed to deliver oxycodone to local tissue at the site of application with minimal blood concentrations and an appropriate safety and side effect profile; and whether oxycodone delivered topically to the primary perceived pain site effectively manage the neuropathic pain experienced by patients.

“It is very encouraging that the TPM-oxycodone patch successfully met its performance objective; delivering oxycodone into the local tissue with minimal systemic exposure and an adverse effects profile similar to placebo,” Dr Murdoch said.

“Given the results of this trial we are re-evaluating our plans for further development of the TPM-oxycodone patch,” Dr Murdoch said. “Although the primary end-point was missed, the learning derived from this study confirms that we have produced a viable patch that can deliver drug to a local site in the desired quantities without significant systemic exposure and with user friendly characteristics.”

Phosphagenics fell 0.1 cents or 12.5 cents to 0.7 cents with 17.6 million shares traded.

VICTORIA GOVERNMENT

The Victoria Government has appointed the $60 million Launchvic board to drive innovation, with apparently just one member known to the biotechnology sector.

The Victoria Minister for Small Business, Innovation and Trade Philip Dalidakis said the board would be chaired by Australia Post chief executive officer Ahmed Fahour and the State Government "had secured some of the country's leading company directors and [chief executive officers] from across the tech, professional and financial services sectors … to help accelerate start-ups, drive new ideas and create jobs".

A media release from Mr Dalidakis said the majority of the board was female in-line with the Labor Government's commitment to have at least 50 percent female representation on public boards.

The Government said that former Circadian chair Dominique Fisher had been appointed to the board, along with Elana Rubin, Jo Burston, Tim Fawcett, Con Frantzeskos, Phillip Kingston, Jane Martino, Rachael Neumann, Kee Wong and Susan Wu.

Mr Dalidakis said that he was "confident the team had the right innovative and entrepreneurial spirit needed to steer the new body and deliver Victorian start-ups what they need".

CYCLOPHARM

Cyclopharm says preliminary findings of on-going trials of Technegas in China show the technology is effective in the diagnosis of chronic obstructive pulmonary disease.

Cyclopharm said that it began the China trial in 2013 and will continue to accept patients until March 31, 2016, with final trial results expected by October 2016.

The company said that initial results indicated that Technegas allowed clinicians to diagnose chronic obstructive pulmonary disease before alternative technologies and effectively measured on-going treatment.

Cyclopharm managing director James McBrayer said the preliminary results "showed Technegas was effective at diagnosing the extent of emphysema in trial patients and at an earlier stage of the disease than standard diagnostic methods".

"It was more accurate at measuring impairment in lung function and therefore better able to monitor the effectiveness of treatment," Mr McBrayer said.

Cyclopharm said that chronic obstructive pulmonary disease was an umbrella term for progressive lung diseases that limited airflow to the lungs, including emphysema and was one of the leading causes of death worldwide.

The company said that chronic obstructive pulmonary disease (COPD) was predicted to become the third leading cause of death worldwide by 2020 and was particularly common in China due to air pollution and high rates of smoking.

"The implications of these findings for Technegas and its utility as a diagnostic tool in a variety of respiratory morbidities are profound," Mr McBrayer said.

"Current lung function tests such as spirometry cannot adequately quantify residual lung function, particularly in the severely damaged lungs often seen in COPD patients," Mr McBrayer said.

The company said that a 2013 study published in the North American Journal of Nuclear Medicine showed that Technegas detected changes in lung ventilation and perfusion before structural lung changes were detected by computed tomography scans and a 2015 study published in the Annals of Nuclear Medicine found that ventilation scans with Technegas could detect ventilatory impairment and airway obstruction even in apparently healthy long-term smokers not shown with spirometry or computed tomography scans.

Cyclopharm climbed six cents or 11.3 percent to 59 cents.

ACRUX

Acrux says that net sales of Axiron fell ($218.2 million) 9.4 percent to $US154.5 million for the 12 months to December 31, 2015 compared to $US170.5 million in the prior year.
While the fall in the Australian dollar implied an almost constant sales value compared to $A218.96 million for the year to December 31, 2014, the US net sales figure has fallen for two years in a row since the high point of $US178.7 million for the 2013 year.
In 2014, sales fell following news that the US Food and Drug Administration was investigating reported cardio-vascular risks in men taking approved testosterone products, despite a European Medicines Agency statement, entitled 'No consistent evidence of an increased risk of heart problems with testosterone medicines' (BD: Feb 4, Nov 24, 2014).
Acrux chief executive officer Michael Kotsanis told Biotech Daily the FDA was in discussion with sponsors to plan a long-term US trail expected to take several years.
Acrux said that Eli Lilly reported Axiron net sales of $US41.6 million (A58.7 million) for the three months to December 31, 2014, down 12.6 percent compared to $US47.6 million for the three months to December 31, 2014.
The company would be entitled to a $US50 million royalty milestone, believed to be when global sales reached more than $US200 million in one calendar year (BD: Jan 31, 2014).
Acrux fell 1.5 cents or 2.1 percent to 70.5 cents.

ELLEX MEDICAL LASERS

Ellex says it expects revenue for the six months to December 31, 2015 to increase 13 percent to $34.8 million with profit before tax of about $1.8 million.
Ellex said that the increase in revenue was due to increased sales of Ellex-branded products in the US, Europe and Japan, the positive impact of a lower Australian dollar against other currencies, discontinuation of contract manufacturing and lower margin third party product sales along with reduction in other third party product sales.
Ellex chief executive officer Tom Spurling said the company was "pleased with our sales growth and improved margins".
"The release of the Integre Pro Scan product in Europe has been good and the continued take up of our innovative Ultra Q Reflex for treating floaters in all regions has been pleasing," Mr Spurling said.
"The improvement in Itrack sales in the US in the last couple of months of the period has also been exciting," Mr Spurling said.
Ellex was up 3.5 cents or 4.7 percent to 78.5 cents.

NANOSONICS

Nanosonics says North American direct sales resulted in record sales of $9.2 million for the three months and $15.6 million for the six months to December 31, 2015.
Last year, Nanosonics began direct sales of its Trophon EPR ultra-sound probe cleaning system, along with distribution by GE Healthcare (BD: Feb 6, 2015).
Today, the company said that the sales revenue of $9.12 million for the three montsh to December 31, 2015 was up 41 percent on the prior quarter "primarily driven by strong sales through the Nanosonics' direct operations in North America as awareness and demand for Trophon continues to grow".
"Our direct operations in North America continue to make excellent progress generating awareness, sales and strong pipeline growth," Nanosonics said.
Nanosonics climbed 16.5 cents or 9.4 percent to $1.915 with 1.85 million shares traded.

HEARTWARE INTERNATIONAL

Heartware says it has terminated its proposed acquisition of Israel's Valtech Cardio and has a "cooperation agreement" with dissenting investor Engaged Capital LLC.

Last year, Heartware's share price fell from a high of $US95 to a low of $US25 following the proposed the merger with Valtech, which develops devices for mitral valve and tricuspid valve regurgitation for about $1.2 billion, but faced opposition from the Newport Beach, California-based Engaged Capital (BD: Sep 2, Oct 6, 2015).

Today, Heartware chief executive officer Doug Godshall said the acquisition was "a unique opportunity to bring together two, complementary portfolios for substantial, high-growth markets and create a broad technology pipeline for the treatment of patients with heart failure".

"While we continue to believe Valtech's portfolio … holds tremendous promise, Heartware finds itself in a different set of circumstances than when we first entered into the agreement," Mr Godshall said.

Mr Godshall said the company would focus on returning the miniature ventricular assist device (MVAD) system to the clinic, enhancing the Heartware ventricular assist device (HVAD) system, with a planned submission for destination therapy and progress the circulatory support pipeline.

"By stepping away from the acquisition, all of our resources will be dedicated to strengthening our existing business," Mr Godshall said.

Heartware said that under the acquisition agreement, it would make a $US30 million loan to Valtech in the form of a convertible promissory note.

Heartware said that under the co-operation agreement with Engaged Capital the two entities would jointly select an additional independent director for the board and establish a business strategy committee, consisting of five directors, including the newly appointed director.

Heartware said that Engaged Capital had agreed to withdraw its previously nominated slate of directors for election at the annual meeting and would not pursue its solicitation of proxies in opposition to the Valtech transaction.

Engaged Capital chief investment officer Glenn Welling said his company was "pleased to have reached an amicable resolution with Heartware following the termination of the Valtech transaction".

Heartware said that its annual general meeting was historically held in June, but had not yet been scheduled.

Last night on the Nasdaq, Heartware climbed $US3.40 or 9.86 percent to $US37.90 ($A53.43, equivalent to $1.53 before it left the ASX) with 1,772,987 shares traded.

BIOTECH DAILY APPENDIX 4C REPORTS

Biotech Daily reports all the significant announcements to the ASX.

Biotechnology companies bleeding money is not news, unless the company involved has less than two quarters of cash.

When companies clearly explain that they have equity draw-down facilities, loans or are about to have a capital raising, or funds are expected, Biotech Daily will not report their Appendix 4C statement.

Where there is no explanation or it is not clear and the company has less than six months of cash reserves, it will be reported, as will maiden revenues or profits.

Companies reporting after the close of business will be reported in the following edition.

David Langsam, Editor

PHARMAUST

Pharmaust says its net operating cash burn for the three months to December 31, 2015 was $826,000 with cash at the end of the quarter of $1,352,000.
Pharmaust said that following the December 31, 2015 cut-off for the Quarterly Report, its subsidiary Epichem received $559,925 from the Geneva, Switzerland-based Drugs for Neglected Diseases Initiative for work on its Chagas disease project.
Pharmaust director Sam Wright told Biotech Daily the company expected to receive a $550,000 R&D Tax Incentive payment in the immediate future.
Pharmaust was up half a cent or 5.6 percent to 9.5 cents.

MEDICAL AUSTRALIA

Medical Australia says its net operating cash burn for the three months to December 31, 2015 was $289,000 with cash at the end of the quarter of $352,000.
Medical Australia has recently divested its animal health business and said that most of the cash burn was attributable to that business.
Medical Australia chief executive officer Darryl Ellis told Biotech Daily that the "underlying human health business is likely to be cash flow positive".
Medical Australia was untraded at six cents.

ANALYTICA MEDICAL

Analytica says it has appointed two more British distributors for the Pericoach intra-vaginal, pelvic floor muscle training system launched in the UK in June 2015.
Analytica said that Savantini had more than 20 years of experience selling pelvic floor products direct to consumers and Elgenia Health was a newly established women's health distributor in London.
Analytica was unchanged at 0.5 cents with 3.5 million shares traded.

3D MEDICAL

3D Medical has appointed Jenni Pilcher as its Australian chief executive officer and global chief financial officer, effective from February 1, 2016.
3D said that Ms Pilcher had "extensive financial leadership and ASX-listed company experience … [with] 10 years as a senior executive in two leading Australian biotechnology companies" and most recently, Ms Pilcher was the chief financial officer and acting chief executive officer of Alchemia, where following a strategic review and in preparation for returning capital to shareholders, she executed the sale of the company's lead asset, a company-wide re-organisation, major contract close-out negotiations, and other asset divestitures involving intellectual property.
3D said that prior to Alchemia, Ms Pilcher spent eight years at Mesoblast as chief financial officer and company secretary and was a lead executive in the completion of four capital raises totalling more than $230 million.
The company said that previously Ms Pilcher held senior finance roles with Spotless Group, Medeva, Cadbury Schweppes and PWC New Zealand.
3D Medical fell 0.2 cents or 2.6 percent to 7.5 cents.