Biotech Daily

Tuesday May 19, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PRIMA UP 55%, PATRYS DOWN 9%**

*** PRIMA 'FINAL DATA BACKS CVAC FOR CANCER, PARTNER WANTED'**

*** ELLEX: '2RT FOR AMD REGENERATES RETINAL CELLS'**

*** FDA APPROVES PRO MEDICUS IMAGING MOBILE 'PHONE APPLICATION**

*** PHARMAXIS DETAILS NEW DIRECTION**

*** PHOSPHAGENICS 33% REMUNERATION 1st STRIKE, NAME CHANGE**

*** PHARMAUST: '2nd DOG CANCER BIOMARKER RESPONSE'**

*** NUSEP TO SELL POLYACRYLAMIDE GEL MANUFACTURING BUSINESS**

*** PROTEOMICS HIRES JOHN MORRISON FOR BUSINESS DEVELOPMENT**

*** IDT LOSES DIRECTOR DAVID WILLAMS**

MARKET REPORT

The Australian stock market fell 0.77 percent on Tuesday May 19, 2015 with the S&P ASX 200 down 43.7 points to 5,615.5 points. Thirteen of the Biotech Daily Top 40 stocks were up, 20 fell, five traded unchanged and two were untraded. All three Big Caps were up.

Prima was the best, up 1.2 cents or 54.55 percent to 3.4 cents with 110.0 million shares traded, followed by Antisense up 14.3 percent to 12 cents with 235,648 shares traded.

Compumedics climbed 9.3 percent; Acrux and IDT were up more than five percent; Ellex and Pharmaxis were up four percent or more; Benitec and Prana were up more than three percent; Impedimed and Resmed rose more than two percent; Admedus, Universal Biosensors and Viralytics were up more than one percent; with Cochlear and CSL up by less than one percent.

Patrys led the falls, down 0.1 cents or 9.1 percent to one cent with 410,000 shares traded.

Analytica and Starpharma lost more than five percent; Biotron, Cellmid, Clinuvel and Oncosil fell four percent or more; Actinogen and Mesoblast were down more than three percent; Atcor and Genetic Technologies shed more than two percent; Avita, Bionomics, Nanosonics, Neuren, Osprey, Sirtex and Tissue Therapies were down more than one percent; with Medical Developments and Psivida down by less than one percent.

PRIMA BIOMED

Prima says its phase II trial of CVac for ovarian cancer has shown “a clear trend” for an improvement in overall survival over standard-of-care in second remission patients.

Prima said that there was “a clinically meaningful improvement” in the subset of 20 second remission patients in the 63-patient CAN-003 trial, in which the median overall survival for standard-of-care patients was 25.53 months, which was consistent with current literature, but patients treated with CVac did not reach a median after 42 months with study completion and closure.

The company said that although the result was not statistically significant the data “suggests a striking improvement ... [and] implies at least a 16 months median survival advantage for second remission patients when treated with CVac”.

Prima chairman Lucy Turnbull said the final clinical data was “most encouraging for cancer patients in second remission [and] our concerted focus will now be to find a development partner to make CVac widely available to cancer sufferers”.

Prima said that the data was consistent with the statistically significant progression-free survival data for second remission patients from CAN-003, with a median progression-free survival for CVac of greater than 12.91 months, compared to a median progression-free survival of 4.94 months for the control group ($p = 0.04$) which the company said implied an eight month median progression-free survival advantage for second remission patients treated with CVac. (BD: May 15, 2014).

In 2013, Prima said that top-line analysis of the CAN-003 trial failed to show significant progression-free survival, which led to a change of endpoint for the phase II/III CAN-004 trial to overall survival and this year Prima closed its CVac programs to prioritize the immunotherapy products acquired with Immutep SA (BD: Sep 19, 2013; Feb 27, 2015).

Prima chief executive officer Marc Voigt said the CAN-003 data showed “a consistent and sustained trend for improvement over the years in progression-free survival and also overall survival” supporting further development under licence to an industry partner.

Prima climbed 1.2 cents or 54.55 percent to 3.4 cents with 110.0 million shares traded.

ELLEX MEDICAL LASERS

Ellex says that additional scientific research validates the method of action of its retinal rejuvenation therapy (2RT) for early age-related macular degeneration.

Ellex said that the research was presented at the April 2015 annual meeting of the Association for Research in Vision and Ophthalmology in Denver, Colorado and investigated the effect of 2RT on cultures of animal retinal pigment epithelium, the layer of cells responsible for maintaining and nourishing the retina.

The company said that the research found that directly following treatment by 2RT of the targeted retinal pigment epithelium cells, the surrounding surviving cells grew into the vacated spaces and stimulated expression of a range of protein factors, triggering a regenerative effect on nearby retinal pigment epithelium cells.

Ellex chief executive officer Tom Spurling said the research confirmed the positive cellular response induced by 2RT validating its previously postulated method of action.

“Building on the work undertaken previously at the Centre for Eye Research Australia and the University of Melbourne, the research ... continues to validate the growing body of clinical and scientific evidence for 2RT in the treatment of early-stage [age-related macular degeneration],” Mr Spurling said. “We are particularly excited that this regenerative process may offer the potential for 2RT to emerge as a platform technology that could provide additional, alternative therapeutic applications.”

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

PRO MEDICUS

Pro Medicus says the US Food and Drug Administration has provided 510 (k) clearance for its Visage Ease Pro mobile telephone application technology.

Pro Medicus said the Visage Ease Pro had been certified for diagnostic interpretation of all imaging modalities, apart from mammography, which required higher screen resolution than current mobile devices can support.

Pro Medicus chief executive officer Dr Sam Hupert said that with the Visage Ease mobile telephone application "we lead the pack in terms of speed and functionality for review access of images".

"Our new Pro version has raised the bar even further, incorporating the ability to quickly check the calibration of the [device] screen ... means that radiologists and allied physicians that require full diagnostic capability on the go can now have it on their mobile device," Dr Hupert said. "This enables them to securely interpret images no matter how large they are anywhere using Visage technology."

Pro Medicus said that Visage Ease Pro included numerous image manipulation features, display of non-medical and non-diagnostic images such as photos, support for recording voice memos and the ability to upload photo attachments to studies on Visage 7.

"We join only a handful of other mobile applications that have received FDA approval but we believe ours is the only FDA-approved mobile solution that is an integral part of a total enterprise imaging platform," Dr Hupert said.

Pro Medicus said the technology had been approved for use in Australia, Canada and Europe and the Visage Ease Pro would be available as a free download from the Australian Apple application store in June, 2015.

Pro Medicus was up 12 cents or 5.8 percent to $2.20.

PHARMAXIS

Pharmaxis says it has changed direction to focus on innovation and partnering.

Pharmaxis said that it had partnered Bronchitol in major markets, cut expenses and employee numbers and sold as PXS4728A to Boehringer Ingelheim (BD: May 18, 2015).

Pharmaxis chief executive officer Gary Phillips said that "restructuring Pharmaxis and withdrawing from a direct commercial presence in global markets whilst preserving value and creating the foundations for future growth has been a significant challenge".

"We have now put Bronchitol on a path to profitability and reduced our cash burn, in order to focus on earlier stage development projects such as the SSAO and LOXL2 inhibitor programs," Mr Phillips said.

Pharmaxis said it would "build a regional biotech centre of excellence in fibrosis and inflammation" developing multiple drugs from an in-house amine oxidase platform developed to phase I or phase II; collaborate to de-risk and accelerate internal and external programs; and licence to major pharmaceutical companies with attractive first-in-class drugs post phase I or phase II trials.

The company said it had three additional drug programs in its pipeline and held $62 million in cash at March 31, 2015.

Pharmaxis chairman Malcolm McComas said that yesterday's Boehringer transaction was "a new chapter for Pharmaxis and validates both our scientific and partnering capability".

"By more than doubling our cash reserves it also gives us the opportunity to realize significant value for shareholders, not only from the PXS4728A deal, but also Bronchitol and our research pipeline," Mr McComas said.

Pharmaxis was up one cent or four percent to 26 cents with 20.5 million shares traded.

PHOSPHAGENICS

Phosphagenics has failed to change its name and earned a remuneration report first strike at its annual general meeting, yesterday.

Phosphagenics posted its notice of meeting to the ASX at the end of its 120-page annual report at 5.20pm on Friday April 17, 2015.

The document was not market “market sensitive” and appears to have been purged by Commsec from its Watchlists Announcements page over that weekend.

Biotech Daily apologizes for missing the notice of meeting which contained resolutions to approve a conditional rights plan and the grant of 15,000,000 conditional rights to chief executive officer Dr Ross Murdoch, the re-election of directors Lawrence Gozlan, Dr Greg Collier and Peter Lankau, as well as a name change from Phosphagenics to Alyptus Biotechnology.

Today, Phosphagenics said that the special resolution to change the name, which required 75 percent support, was opposed by 184,890,031 proxy votes (31.94%) and supported by 393,903,184 proxy votes (68.05%).

The company said that opposition to the remuneration report was by a slightly greater margin with 169,243,803 votes (32.79%) opposing and 346,888,535 votes (67.21%) in favor, with a similar number opposing the election of Mr Lankau, who required a simple 50 percent majority.

Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and at the later meeting and if passed by more than 50 percent of votes the directors must stand for re-election at a subsequent meeting within 90 days.

Phosphagenics most recent Appendix 3B new issue announcement said the company had 1,020,465,957 shares on issue, meaning the votes against the name change amounted to 18.1 percent of the company, sufficient to requisition extraordinary general meetings.

The company said that three resolutions relating to 15,000,000 conditional rights and benefits to Dr Murdoch were opposed by more than 63.4 million votes but supported by more than 403.5 million votes, with Dr Collier elected with 526.6 million votes (95.0%) in favor and 27.5 million votes (5.0%) against.

Last week, Mr Gozlan resigned from the company to focus on his other business interests and commitments and the election resolution was withdrawn (BD: May 12, 2015).

In its explanatory statement of the meeting resolutions, Phosphagenics said that it should change the name because a review of the company found “that the security ticker code of POH had numerous connotations; there was confusion about the correct spelling of Phosphagenics, especially phonetically; and separation from former CEO controversy”.

Last year, the former chief executive officer Dr Esra Ogru was gaoled with former executive Dr Robert Gianello and AOD9604 co-inventor Dr Woei-Jia Jiang for their theft of $6 million from the company (BD: Nov 7, 2014).

Phosphagenics rose 0.1 cents or 4.2 percent to 2.5 cents with 2.5 million shares traded.

PHARMAUST

Pharmaust says that a second dog has responded well to PPL-1, demonstrating tumor marker p70S6K suppression (BD: May 1,2015).

Pharmaust said that suppression was about 20 percent and 55 percent after three days and seven days of treatment, respectively, providing further evidence that PPL-1 was active in canines by suppressing a tumor marker.

Pharmaust fell 0.1 cents or 8.3 percent to 1.1 cents with 4.8 million shares traded.

NUSEP HOLDINGS

Nusep says it will exit the pre-cast polyacrylamide gel manufacturing business by the end of the year and is seeking expressions of interest from potential buyers.
Nusep said that the decision followed a strategic review of business opportunities after a major customer acquired a company with an established pre-cast polyacrylamide gel manufacturing capacity and would source their pre-cast gels from their acquisition.
The company said it was better served by focusing on developing its other business units, in particular Spermsep, its technology for sperm processing for use in assisted reproductive technologies.
Nusep said that sales of pre-cast polyacrylamide gels, a consumable primarily used by research scientists, were worth $701,380 in 2014, with the main market in the US, but sold to customers in the UK, Germany, Taiwan, Japan and Australia.
Nusep was untraded at four cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has appointed John (Chuck) Morrison as the head of global business development.
Proteomics said that Mr Morrison has more than 36 years experience in the life sciences, biotechnology and diagnostic industries and was a key addition to the senior management team.
The company said that Mr Morrison would source and execute commercialization opportunities for products derived from its proteomics-based technology platform.
Proteomics said that Mr Morrison had executed licencing deals and acquisitions in the life sciences sector worldwide, including a lead role in the acquisition of the Shanghai-based Symbio Diagnostics.
The company said that Mr Morrison was based in Boston, Massachusetts and was well-placed in the US life sciences and biotech markets and other major markets.
Proteomics said that previously Mr Morrison held senior roles at NEN Life Sciences and DuPont, and in business development at Perkinelmer.
Proteomics said that Mr Morrison played an integral role in its recent agreement with China's Newsummit Biopharma Co to commercialize its test for diabetic kidney disease.
Proteomics was up half a cent or 2.5 percent to 20.5 cents.

IDT AUSTRALIA

IDT says that director of five years David Williams has resigned effective from today "to devote more time to his other business interests".
Mr Williams is the principal of advisory firm Kidder Williams, as well as chairman of Medical Developments and Polynovo.
IDT climbed 1.5 cents or 5.9 percent to 27 cents.