Biotech Daily

Tuesday April 30, 2013

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: PHOSPHAGENICS UP 9%, PHYLOGICA DOWN 13%**

*** WEHI, QIMR BROAD MALARIA VACCINE TO BEGIN TRIALS IN 2014**

*** SUDA SUB-LINGUAL ARTIMIST 'SUPERIOR TO IV QUININE FOR MALARIA'**

*** PHARMAUST TO ACQUIRE PITNEY FOR 3 CANCER PLATFORMS**

*** US SALES TAKE HEARTWARE Q1 REVENUE UP 87% TO $47.5m**

*** PSIVIDA, ALIMERA ILUVIEN AVAILABLE TO UK PRIVATE DME PATIENTS**

*** GENETIC TECHNOLOGIES LICENCE FOR GENETICS & IVF INSTITUTE**

*** CHINA PATENT FOR IMUGENE'S LINGUET**

*** CORRECTION: PHOSPHAGENICS, CALZADA & AOD9604**

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

*** MEDICAL AUSTRALIA HAS ONE QUARTER CASH**

*** GENETIC TECHNOLOGIES LESS THAN SIX MONTHS CASH, REVENUE**

*** HEALTHLINX REQUESTS FUNDING SUSPENSION**

*** NORTHCAPE BELOW 5% IN PHARMAXIS**

*** WILSON HTM REDUCES 1% IN UNIVERSAL BIOSENSORS**

MARKET REPORT

The Australian stock market was up 1.28 percent on Tuesday April 30, 2013 with the S&P ASX 200 up 65.4 points to 5,191.2 points. Eight of the Biotech Daily Top 40 stocks were up, 22 fell, seven traded unchanged and three were untraded. All three Big Caps were up.

Phosphagenics was the best, up one cent or 9.1 percent to 12 cents with 654,217 shares traded. Heartware climbed 8.05 percent; Nanosonics and Patrys were up more than three percent; Mesoblast and Reva rose more than two percent; with Acrux up one percent.

Phylogica led the falls for the second day in a row, down 0.2 cents or 13.3 percent to 1.3 cents with 86,950 shares traded. Impedimed lost 9.7 percent; Osprey fell 8.2 percent; Ellex and Tissue Therapies were down more than seven percent; Neuren and Psivida fell more than five percent; Optiscan fell 4.6 percent; Avita and Starpharma were down more than three percent; Alchemia, Atcor, Bionomics, Clinuvel, Genetic Technologies, Living Cell, Prana, Prima, QRX and Sirtex shed more than two percent; with Anteo and Medical Developments down more than one percent.

THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH
QUEENSLAND INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says the first malaria vaccine to combat the many variants of malaria will begin clinical trials in 2014.

The Institute said that the vaccine, developed with researchers from Queensland Institute of Medical Research, used a genetically-modified strain of the malaria parasite to protect people at risk from malaria infection.

WEHI said the team was by Dr Krystal Evans, Prof Louis Schofield and Prof Alan Cowman with QIMR's Prof James McCarthy.

WEHI said that the vaccine targeted the blood stage of malaria infection, the stage responsible for symptoms such as headache, fever, shivering and joint pain.

Dr Evans said the design of the genetically attenuated parasite vaccine was based on years of research at the Walter and Eliza Hall Institute which had identified critical molecules in the malaria parasite that could be recognized by the immune system.

The Institute said that the manufacture and trial of the genetically attenuated parasite (GAP) vaccine was supported by an Australian National Health and Medical Research Council development grant.

"The funding will allow us to firstly manufacture the vaccine in sufficient quantities, and to high enough standards for human trials," Dr Evans said.

"We will then have the opportunity to test how effective the vaccine is in inducing a protective immune response against malaria," Dr Evans said.

"If these trials are successful, the next stage will be to develop the vaccine further, by adding additional features to prevent malaria transmission, such as modifying it to match regional and species variants of the malaria parasite," Dr Evans said.

The institute said that the genetically attenuated parasites to be used in the trial were being manufactured at its Melbourne facility, the only one capable of producing genetically-altered malaria parasites that complied with the good manufacturing practice guidelines required for human clinical trials.

Prof Schofield said the genetically attenuated parasite vaccine was an important new approach to combating malaria.

"There is a clear need for a vaccine against malaria," Prof Schofield said.

"In many parts of the world, the malaria parasite has developed resistance to anti-malarial medications," Prof Schofield said.

"An effective vaccine could offer people in malaria-endemic regions long-lasting protection against this devastating disease," Prof Schofield said.

"The [genetically attenuated parasite] vaccine has the ability to be modified to suit the variability that occurs in malaria between regions and over time," Prof Schofield said.

Prof Schofield said the NHMRC development grant allowed the group to develop vaccine research projects from the laboratory through to clinical trials, with seed funding provided by the Bill & Melinda Gates Foundation.

WEHI said that malaria killed about 700,000 people a year, mostly children aged under five years and pregnant women.

The Institute said that every year, hundreds of millions of people were infected with the malaria parasite, Plasmodium, which was transmitted through mosquito bites.

WEHI said that half the world's population was at risk of contracting malaria, with the disease being concentrated in tropical and subtropical regions including many of Australia's near neighbors.

The Institute said that despite the urgent need for a malaria vaccine, no effective vaccine currently exists.

SUDA (FORMERLY EASTLAND MEDICAL SYSTEMS)

Suda says that its 151-paediatric subject, phase III trial of sub-lingual Artimist has shown significant superiority to intravenous quinine.

Suda said that the trial in children with severe or complicated falciparum malaria, or uncomplicated falciparum malaria with gastrointestinal complications showed that 95.6 percent of Artimist patients had reduced parasite counts by more than 90 percent in the first 24 hours, compared with 40.6 percent using intravenous quinine ($p < 0.005$).

Suda said that it clearly met both primary efficacy endpoints, but under secondary endpoints, there was no significant difference in complete cure rates.

The trial report said that there were no serious adverse events related to Artimist, local tolerability was good and there were no adverse events related to local tolerability.

The report said that there were four serious Artimist adverse events and 11 in quinine patients, but “serious adverse events are to be expected in a trial with such sick patients”.

Overall there were no other safety concerns relating to either treatment, the report said.

The trial reports said that while the data was being fully evaluated “we know that these patients had late parasitological failure for a number of reasons which include new/re-infection and recrudescence”.

The report said that the investigators were confirming the reasons for the others and any relationships that may be relevant and the data would be released in the final report.

Suda said that the results “strongly support the potential role that Artimist may be able to play in the early interventional treatment of malaria in these cases”.

The company said that the phase III trial was carried out by Protopharma in malaria endemic areas of Rwanda, Burkina Faso and Ghana over 22 months from November 2010 to September 2012.

Suda said that the study’s primary objective was to demonstrate that sub-lingual Artimist was superior to intravenous quinine in reduction of the parasite counts.

“The study convincingly confirmed this objective,” Suda said.

The company said that the secondary efficacy parameters demonstrated a statistically significant difference between the treatments in both efficacy populations ($p < 0.005$), further demonstrating the superiority of Artimist over IV quinine in clearing parasites.

Suda said that there were 10 early treatment failures for quinine treated subjects and one quinine treated subject required rescue therapy.

The company said that no early treatment failures with Artimist, nor did any subject require rescue therapy.

Suda said that quinine did not appear to be better than Artimist for any of the secondary endpoints included in this study.

The company said that the results provided “a compelling argument for the potential use of Artimist as an early interventional treatment for children with severe or complicated falciparum malaria, or uncomplicated falciparum malaria with gastrointestinal complications”.

Suda quoted the World Health Organisation saying that “the majority of deaths from severe malaria in childhood are caused by the delayed administration of effective anti-malarial treatment [and] there is a relentless deterioration in the clinical condition of a young child with malaria who fails to get effective treatment, with death ensuing in a matter of hours or days”.

Suda said that Artimist had the potential to be an effective pre-referral medication and had the potential to significantly reduce child mortality and potentially the adverse effects suffered by children, particularly within the first 24 hours of infection.

The company said that the trial’s draft report was being finalized by Protopharma.

Suda was up 0.3 cents or 8.3 percent to 3.9 cents with 42.9 million shares traded.

PHARMAUST

Pharmaust says it will acquire Pitney Pharmaceuticals and its three oncology platforms for up to 600 million shares.

Pharmaust said that on completion of due diligence it would raise at least $3 million and it had engaged Peloton Capital to undertake a placement at one cent a share to raise $500,000 to fund costs associated with due diligence and working capital.

Pharmaust said that the Sydney-based Pitney was developing three oncology platforms targeting liver, bowel, ovarian, lung and cervical cancer and one of the platforms was the subject of a research and option agreement for a veterinary product, while a second platform had completed two trials in humans and was ready for a phase II clinical trial.

Pharmaust said that Pitney's strategy was to capitalize on the know-how and experience with existing drugs for new applications, potentially shortening development time through the existing human and veterinary experience and empirical information.

The company said that Pitney had exclusive rights to three oncology platforms from Newsouth Innovations, the commercialization arm of the University of New South Wales.

Pharmaust said the first platform was Albendazole, an anthelminthic drug used in human and veterinary practice and shown to be a potent vascular endothelial growth factor (VEGF) inhibitor and evaluated at the St George Hospital for the treatment of ascites, a condition affecting about 10 percent of abdominal cancers.

The second platform entitled 'Another Anthelminthic Drug' was being investigated for its clinical scope and application in oncology and was the subject of a research and option agreement, while the third platform was the treatment of diseases involving mucin.

Pharmaust said that some abdominal cancers were characterized by the presence of large amounts of mucin, a gelatinous substance that reduced the efficacy of anti-cancer drugs and the removal of the tumor-associated mucin proved a challenge.

The company said that Pitney had the licence to a formulation that dissolved the mucin in-situ and potentially allowed for more effective chemotherapy.

Pharmaust said it would appoint Dr Roger Aston and Prof David Morris as directors and Bryant Mclarty would stand down on or about completion of the transaction.

The company said it expected to hold a shareholder meeting to approve the transaction in late June 2013.

Pharmaust was up 0.4 cents or 44.4 percent to 1.3 cents with 6.2 million shares traded.

HEARTWARE INTERNATIONAL,

Heartware says that revenue for the three months to March 31, 2013 was up 87 percent to $US49.2 million ($A47.5 million) compared to the previous corresponding period.

Heartware said the three month period was "the first full quarter of US commercialization".

Heartware chief executive officer Doug Godshall said that the results "reflect positive initial trends in the commercial launch of the Heartware Ventricular Assist System in the US, following approval from the Food and Drug Administration in November 2012, and continued strong support from our international customers".

"During the first quarter of 2013, 482 HVAD pumps were sold globally, an increase from 298 units in the first quarter of 2012 and more than our previous high quarterly total of 345 units in the fourth quarter of 2012," Mr Godshall said.

Heartware said that in the first three months of 2013, US revenue was $US26.2 million, an increase of about 300 percent compared to the first quarter of 2012 and that revenue from international markets, generated through the sale of 244 units, was $US23.1 million, an increase of about 16 percent from $US19.9 million in the first three months of 2012.

Heartware was up 19 cents or 8.05 percent to $2.55.

PSIVIDA

Psivida says that its Iluvien sustained release treatment of chronic diabetic macular oedema is available to private patients in the UK, through its licensee Alimera Sciences.
Psivida said that Alimera had also submitted a patient access scheme application to the UK National Institute for Health and Care Excellence (NICE) for consideration of the guidance under rapid review.
The company said that the NICE appraisal committee would assess the likely impact of the Iluvien patient access scheme and determine whether an update to its previously final guidance was warranted.
Psivida said that if the patient access scheme was accepted by NICE, Alimera reported that Iluvien would be funded for chronic diabetic macular oedema (DME) patients in England and Wales through the National Health Service.
The company said that appraisal committee was scheduled to meet on May 15, 2013 to discuss the submission with an expected 30-day review period to follow.
Psivida chief executive officer Dr Paul Ashton said the company was “pleased that Iluvien is now available in the UK”.
“This marks the first availability of a sustained release therapy for patients who suffer from DME and who have not responded to conventional therapies,” Dr Ashton said. “We are hopeful that the patient access scheme will be approved and make Iluvien available to a larger group of chronic DME patients.”
Psivida fell 12 cents or 5.7 percent to $2.00.

GENETIC TECHNOLOGIES

Genetic Technologies says it has executed a settlement agreement with the Fairfax, Virginia-based Genetics & IVF Institute.
Genetic Technologies said that in late 2012, it filed suit against Genetics & IVF Institute in the US District Court for the Eastern District of Virginia, under its assertion program relating to the company’s non-coding DNA patents and with the litigation resolved, the action had been dismissed (BD: Dec 21, 2012).
The company said the precise commercial terms of the agreement could not be disclosed.
Genetic Technologies fell 0.2 cents or 2.6 percent to 7.6 cents.

IMUGENE

Imugene says that China has accepted a patent application for its Linguet drug delivery technology.
Imugene said that the Chinese application provided protection “around Linguet’s formulations and other specific excipients for a class of drugs that prevent the loss of bone mass, known as bisphosphonic acids and bisphosphonates … used to treat conditions such as osteoporosis and multiple myeloma” and followed the same patent formulation allowance in Japan last month.
Imugene said Linguet enabled the active ingredient to be absorbed into the bloodstream through the buccal mucosa, or under the tongue.
Imugene executive director Dr Nick Ede said the expansion of the patent portfolio in Japan and China was “a significant step in our commercialization strategy”.
“Not only does it demonstrate the strength of our novel Linguet technology, but it enables us to explore two lucrative Asian markets ahead of the anticipated regulatory approval of Linguet vitamin D next year,” Dr Ede said.
Imugene was up 0.2 cents or 25 percent to one cent with 1.2 million shares traded.

PHOSPHAGENICS, CALZADA

In the edition of April 26, 2103 in which Calzada responded to what it called errors and misrepresentations on the anti-obesity drug AOD9604, Biotech Daily reported that the UK Boots shops had discontinued stocking the Phosphagenics rub-away-the-fat anti-cellulite Bodyshaper crème containing the allowed cosmetic renamed AOP9604.
Phosphagenics chief executive officer Dr Esra Ogru has told Biotech Daily that the UK version of Bodyshaper did not contain AOP9604, although the variant sold in South Korea does contain the compound.
Dr Ogru said that Bodyshaper was not “rejected by UK retail chain Boots” as reported in the edition, but had been removed from its shops and remained available for on-line orders (BD: Sep 26, 2012).
Biotech Daily apologizes for the errors and has rubbed away the sub-editor responsible.
Calzada fell 0.9 cents or 9.6 percent to 8.5 cents.
Phosphagenics was up one cent or 9.1 percent to 12 cents.

BIOTECH DAILY APPENDIX 4C REPORTS

Biotech Daily reports all significant biotechnology company announcements, but biotechs burning money is not news, unless the company has less than two quarters of cash.
When companies clearly explain that they have equity draw-down facilities or loans or are about to have a capital raising, 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

MEDICAL AUSTRALIA

Medical Australia says its net operating cash burn for the three months to March 31, 2013 was $175,000 with cash at the end of the quarter of $190,000.
Medical Australia provided no further information.
Medical Australia was untraded at one cent.

GENETIC TECHNOLOGIES

Genetic Technologies says its net operating cash burn for the three months to March, 2013 was $2,624,225, with cash at the end of the quarter of $3,142,555.
Genetic Technologies chief executive officer Alison Mew told Biotech Daily that the company was aware of the cash situation and had announced several licences along with increased Brevagen sales and the disposal on non-core assets.

HEALTHLINX

Healthlinx has requested a voluntary suspension pending the release of an announcement relating to funding.
Healthlinx said that the funding facility announced last month “has not eventuated for reasons beyond the control of the company” (BD: Mar 21, 2013).
Healthlinx last traded at 0.1 cents.

PHARMAXIS

Northcape Capital says it has ceased its substantial shareholding in Pharmaxis, reducing its holding from 14,272,395 shares (6.23%) to 6,151,496 shares (1.99%).
The Sydney-based Northcape said that since its last notice in 2011, it bought 8,472,321 shares for $4,523,879 or an average price of 53.4 cents a share and sold 16,593,220 shares for $7,650,785 or an average price of 46.1 cents a share (BD: Oct 10, 2011)
Pharmaxis was unchanged at 14.5 cents with 3.4 million shares traded.

UNIVERSAL BIOSENSORS

Wilson HTM Investment Group has reduced its substantial holding in Universal Biosensors from 12,547,943 shares (7.89%) to 11,314,750 shares (6.5%).
Wilson HTM said that between October 28, 2011 and April 24, 2013, “individually managed accounts” along with Wilson HTM funds bought and sold shares.
Wilson HTM said that the largest sale was 50,403,414 shares for $37,267,622 or an average price of 73.9 cents a shares, while the largest purchase was 51,143,244 shares for $37,577,776 or an average price of 73.5 cents a share.
Biotech Daily understands that Wilson HTM has collectively reported large numbers of transactions within its funds under the individual purchase and sale statements.
Universal Biosensors was up half a cent or 0.8 percent to 61.5 cents.