Biotech Daily

Thursday March 31, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: USCOM UP 20%, GENETIC TECHNOLOGIES DOWN 9.5%**

*** REDHILL: 'PHASE III RHB-105 (GIACONDA HELICONDA) SUCCESS'**

*** PERKINS INSTITUTE DEVELOPS BLOOD VESSEL REPAIR DRUG**

*** RHINOMED RAISES $4m, SHARE PLAN**

*** THAI STUDY: 'USCOM REDUCES PAEDIATRIC MORTALITY'**

*** RESAPP: 'INCREASED DATA SETS IMPROVE DIAGNOSES'**

*** JOURNAL ARTICLE BACKS PATRYS CANCER DRUG ACQUISITION**

*** 3D EGM VOTES TO BECOME MACH7, BOARD CHANGES**

*** BIOXYNE BACK TO THE PROBIOMICS PROBIOTIC FUTURE**

*** REGAL FUNDS TAKES 7% OF ADHERIUM**

MARKET REPORT

The Australian stock market was up 1.45 percent on Thursday March 31, 2016 with the ASX200 up 72.5 points to 5,082.8 points. Twenty-five of the Biotech Daily Top 40 stocks were up, five fell, seven traded unchanged and three were untraded. All Big Caps rose.

Uscom was the best, up 3.5 cents or 20 percent to 21 cents with 103,526 shares traded, followed by Pharmaxis up 10.2 percent to 27 cents with 1.3 million shares traded.

Atcor, Bionomics and Mesoblast climbed more than six percent; Avita, Polynovo and Tissue Therapies were up five percent or more; Acrux was up 4.3 percent; Admedus, IDT, Living Cell, Medical Developments and Oncosil were up more than three percent; Actinogen, Compumedics, Nanosonics, Sirtex, Starpharma and Viralytics rose more than two percent; Cochlear, CSL, Osprey, Pro Medicus and Universal Biosensors were up more than one percent; with Clinuvel, Ellex and Resmed up by less than one percent.

Genetic Technologies led the falls, down 0.2 cents or 9.5 percent to 1.9 cents with 570,000 shares traded. Benitec and Psivida fell more than four percent; with Impedimed and Reva down more than one percent.

REDHILL BIOPHARMA, GIACONDA

Israel's Redhill says a phase III trial of RHB-105 has shown safety and superior efficacy for Helicobacter pylori infection over the standard-of-care.

Redhill's head of business development and licencing Adi Frish told Biotech Daily that RHB-105 was based on Giaconda's Heliconda for Helicobacter infection but the drug had been developed and further refined into a single capsule by his company.

Mr Frish said that Giaconda major shareholder and chief medical officer Prof Thomas Borody continued as an adviser to Redhill.

In August 2010, Giaconda sold its Myoconda, Heliconda and Picoconda patents to Israel's Redhill Biopharma for $US500,000 plus seven percent of net sales that gave Redhill the charge over Giaconda's 78,373,505 shares (BD: Aug 17, 2010).

In 2010, Giaconda said the Heliconda formulation was developed by Prof Borody as a therapy for patients who failed conventional therapy for the Helicobacter pylori infection (BD: Apr 23, 2010).

Earlier this month, Redhill said that the 118-patient, phase III study met its primary endpoint of superiority over historical standard-of-care eradication rate levels of 70 percent ($p < 0.001$).

The company said that the RHB-105 achieved 89.4 percent efficacy in eradicating Helicobacter pylori infection in all patients who received at least one dose of randomized study treatment and underwent a test of cure at visit four, 28 to 35 days after completion of treatment.

Redhill said that a subsequent open-label treatment of patients in the placebo arm with standard-of-care therapy demonstrated a 63 percent eradication rate.

The company said that a meeting with the US Food and Drug Administration was scheduled for April 2016 to discuss the confirmatory phase III study with RHB-105, planned to be initiated by October 2016 and the path for approval of RHB-105 as a potential best-in-class, first-line therapy for Helicobacter pylori infection.

Redhill said that RHB-105 had fast-track development status, priority review and extended market exclusivity for a total of eight year, with the global and US market potential for Helicobacter pylori eradication therapies estimated at $US4.83 billion and $US1.45 billion, respectively.

The company said that RHB-105 was "a new and proprietary fixed-dose oral combination therapy of two antibiotics and a proton pump inhibitor in an all-in-one oral capsule with a planned indication for the treatment of Helicobacter pylori infection".

Redhill said that Helicobacter pylori bacterial infection was a major cause of chronic gastritis, peptic ulcer disease, gastric cancer and mucosa associated lymphoid tissue lymphoma.

In 2011, Giaconda was the subject of a deed of company arrangement and was delisted from the ASX in 2013 (BD: Apr 21, 2011).

In 2008, Giaconda suspended its phase IIa trial of Hepaconda for non-responsive genotype 1 hepatitis C infection when two key indicators of the disease were not affected by the treatment and the company said that further formulation was warranted before continuing the study (BD: Jul 8, 2008).

Also in 2008, a $40 million investment by Australian Medical Therapy Investments became entangled in Prof Borody's divorce proceedings (BD: Jul 18, Oct 31, 2008).

In 2010, Giaconda agreed sell its Myoconda intellectual property to Australian Medical Therapy Investments for $928,000 (excluding GST) plus five percent of net sales but later terminated the deal (BD: Mar 9, 19; Jun 16, 2010).

Last night on the Nasdaq, Redhill fell 18 US cents or 1.49 percent to $US11.94 with 52,465 shares traded.

THE HARRY PERKINS INSTITUTE OF MEDICAL RESEARCH

The Harry Perkins Institute says its staff have developed a drug to repair blood vessel defects and allow for more targeted and effective cancer drug delivery.

The Perth, Western Australia-based Harry Perkins Institute, formerly the Western Australian Institute for Medical Research, said that the drug LIGHT/TNFSF14 was developed by Prof Ruth Ganss and her team.

The Institute said that current anti-cancer treatments like chemotherapy and immunotherapy, harnessed a person's own killer immune cells, but could struggle to enter a tumor because the blood vessels that fuel the tumor become malformed.

The Institute said that tumors required nutrients and blood vessels were redirected towards the cancer and they developed abnormalities.

The Institute said that Prof Ganss and her team found that smooth muscle cells that lined blood vessels to give them shape and help them pump blood often broke down in tumors, leading to the blood vessel becoming leaky, reducing blood flow and preventing chemotherapy and immune cells travelling into the tumor.

Prof Ganss said the drug developed in her laboratory worked by repairing the smooth muscle cells and returning normal blood flow to the vessels, allowing other anti-cancer drugs to reach the tumor's core.

The research, entitled 'Intratumoral LIGHT Restores Pericyte Contractile Properties and Vessel Integrity' was published in the journal Cell Reports and an abstract is available at: http://www.sciencedirect.com/science/article/pii/S2211124715014163.

"To achieve greater absorption of anti-cancer drugs, the blood vessels are really key," Prof Ganss said.

Prof Ganss said the defect in smooth muscle cells lining blood vessels in cancer could be a catalyst for other problems.

"It could be that once the smooth muscle cells break down and the blood vessels become leaky, cancer cells are able to slip out of the tumors and migrate through the blood stream to spread to different parts of the body," Prof Ganss said.

"We are currently investigating whether our drug could help stem the spread of cancer in a patient by repairing the leaky blood vessels," Prof Ganss said.

RHINOMED

Rhinomed says it has raised $4 million through a two-tranche placement at 2.4 cent a share and will offer a share purchase plan to retail investors.

Rhinomed said that the first tranche of $3,350,000 in shares was made under its placement capacity with the second tranche of $650,000 subject to shareholder approval, with chairman Ron Dewhurst investing $500,000 in the second tranche.

The company said a share purchase plan would allow shareholders at the record date of March 30, 2016 to subscribe for up to $15,000 in shares at 2.4 cents a share.

Rhinomed company secretary Phillip Hains told Biotech Daily that details were being completed for the share plane but he expected it would close about the time of the extraordinary general meeting in mid-May.

The company said that the capital raising was coordinated through Hugh Robertson at Bell Potter in Melbourne.

Rhinomed said that the funds would be used to support the launch of its Mute snoring and sleep technology into the US market and activities in Europe.

Rhinomed fell 0.1 cents or four percent to 2.4 cents.

USCOM

Uscom says that a Thai study shows a 46 percent reduction in mortality for paediatric fluid refractory septic shock patients using its ultrasonic cardiac output monitor.

Uscom said that the Chulalongkorn University Department of Paediatrics and the King Chulalongkorn Memorial Hospital study concluded that 'Uscom had a benefit in evaluation and management [of] paediatric fluid refractory septic shock patients".

"This study showed a decrease in mortality, and increase in achievement goals of [early goal-directed therapy] in the sixth hour, but no difference in length of [paediatric intensive care unit] stay," the poster concluded.

"Moreover, Uscom may help to decrease fluid intake and positive fluid balance compare with previous study," the poster concluded.

Entitled 'Efficacy of non-invasive cardiac monitoring (Ultrasonic Cardiac Output Monitor) guide in management fluid refractory paediatrics septic shock' the poster was presented by staff of the Chulalongkorn University's division of pulmonary and critical care in the department of paediatrics at the Thai Paediatric Respiratory and Critical Care Society Annual Scientific Meeting on March 23, 2016.

Uscom said in a media release that the study, of six month to 14 year olds with severe infections, found Uscom aided treatment in 71 percent of patients, reduced total fluid loading and reduced mortality by a relative 46 percent, from 19 percent to 10.2 percent, since adopting the Uscom 1A and the Lithgow-based University of Notre Dame's critical care leader Prof Brendan Smith's approach to septic shock management.

A table provided with the media release showed that septic shock mortality at the King Chulalongkorn Memorial Hospital fell from 42 percent for the period 2005-2009 to 19 percent in 2009-2011, falling further to 11 percent in 2013-2014, following the introduction of the Uscom 1a monitor and to 10.2 percent in 2014-2015.

Uscom said that Prof Smith presented similar findings at the Society of Critical Care Medicine Annual Scientific meeting in 2012 and was nominated for Australian of the Year in 2014 for his work on implementing improved septic shock management in regional Australia.

The company said that similar results were published by Kings College in London in 2013 where Uscom guided management had been implemented and reduced paediatric sepsis mortality by a relative 35 percent from 17 percent to 11 percent.

Prof Smith said the results were "consistent with our findings and the findings of others worldwide".

"The early and accurate measurement of haemodynamics using Uscom allows us to non-invasively and rapidly initiate appropriate treatment, saving vital minutes and patients' lives," Prof Smith said.

Uscom said that sepsis killed more than six million children and neonates a year, while fluid refractory septic shock, associated with severe infections, was responsible for the death of about 70 percent of all children who die worldwide.

Uscom executive chairman Prof Rob Phillips said that if his company's monitor "was adopted worldwide and achieved only a 35 percent reduction in mortality, this could save over two million children a year".

"Sepsis is a serious global health issue and Uscom is changing the balance," Prof Phillips said.

"It is now the responsibility of public health providers to take notice of the evidence," Prof Phillips said.

"As superbugs become more virulent, the significance of Uscom technology will become more critical," Prof Phillips said.

Uscom was up 3.5 cents or 20 percent to 21 cents.

RESAPP HEALTH

Resapp says that its increased paediatric clinical study dataset has improved its increased lower respiratory tract disease detection from 80 percent to 97 percent.

Resapp said that the study at the Perth, Western Australia-based Joondalup Health Campus and Princess Margaret Hospital had increased the dataset from 338 subjects to 524 subjects.

The company said that the analysis by Prof Udantha Abeyratne's team "reaffirmed the high level of accuracy of Resapp's diagnostic algorithms for the identification of lower respiratory tract disease".

Resapp said that the algorithms were able to correctly detect lower respiratory tract disease in 97 percent of patients initially diagnosed as clear by experienced clinicians using stethoscopes but the patients were finally diagnosed as having a lower respiratory tract disease after additional clinical testing.

Resapp said that the increase in performance from the previously reported 80 percent was "due to the combination of the increased number of subjects considered (37 subjects compared to 24 in the March 2 analysis) and the inclusion of the presence of fever and the presence of runny nose in the algorithm" (BD: Mar 2, 2016).

The company said that its algorithms achieved overall accuracy levels of more than 89 percent when used to differentiate between patients with lower respiratory tract disease and patients with upper respiratory tract infections with no lower respiratory tract involvement and subjects with no discernible respiratory tract disease.

Resapp said that for the differential diagnosis of croup, viral pneumonia, bronchiolitis and upper respiratory tract infections, its algorithms achieved accuracy levels between 90 percent and 98 percent on the larger dataset.

The company said that overall sensitivity, specificity and accuracy levels obtained on the larger dataset were generally similar to the previously reported results.

Resapp said that the research team performed a preliminary evaluation of the algorithms' ability to separate bacterial and atypical pneumonia from viral pneumonia and the preliminary results showed that its algorithms could achieve accuracy of between 89 percent and 92 percent for the separation of these different types of pneumonia.

The company said that the results could change as additional patients with bacterial and atypical pneumonia were added to the dataset.

Resapp chief executive officer Dr Tony Keating said the company was "pleased to again report high levels of accuracy on a dataset that is more than 50 percent larger than the previously used dataset".

"These updated results reaffirm the algorithm's clinical accuracy right before we enter the pivotal studies needed for our upcoming premarket submission to the US Food and Drug Administration," Dr Keating said.

"In addition, these preliminary results for the separation of bacterial and atypical pneumonia from viral pneumonia are very exciting as they demonstrate the power of Resapp's algorithm in supporting clinicians in making critical decisions for patient treatment," Dr Keating said.

Resapp said it intended to continue enrolment in the current paediatric study due to the high value of the data collected.

Resapp fell one cent or 3.85 percent to 25 cents with 7.7 million shares traded.

PATRYS

Patrys says a journal article supports the cell nucleus-penetrating mechanism of action of Deoxymab and 5C6 licenced from Yale University this week (BD: Mar 29, 2016).
Patrys said that the Deoxymab, or 3E10, and 5C6 antibodies were originally isolated from lupus-prone mice.
The company said that the Deoxymab antibody was first considered for use as a vaccine for patients with systemic lupus erythematosus and was safely tested in humans in 1999, but in the evaluation process Deoxymab was found to have the unusual capacity to penetrate into live cell nuclei and bind DNA.
Patrys said that the mechanisms by which Deoxymab and similar antibodies cross the cell membrane were diverse, but it was discovered that once inside the nucleus they could inhibit DNA repair or directly damage DNA, making them promising potential cancer therapeutics because the effects were toxic to cancer cells with defects in DNA repair and increased the sensitivity of cancer cells to radiation and chemotherapy.
The company said that the review article examined the role of DNA-damaging antibodies, such as Deoxymab and 5C6, in lupus and said the antibodies might suppress the growth, and reduce the risk, of development of certain cancers and were a promising new approach to cancer therapy.
Patrys said that Deoxymab and 5C6 were the focus of preclinical development programs sponsored by Patrys.
The journal article is entitled 'DNA-damaging autoantibodies and cancer: the lupus butterfly theory' and an abstract is available at:
http://www.nature.com/nrrheum/journal/vaop/ncurrent/full/nrrheum.2016.23.html.
The article said that auto-antibodies reactive against host DNA were detectable in the circulation of most people with systemic lupus erythematosus.
"The long-held view that antibodies cannot penetrate live cells has been disproved," the abstract said.
"A subset of lupus autoantibodies penetrate cells, translocate to nuclei and inhibit DNA repair or directly damages DNA," the abstract said.
"The result of these effects depends on the micro-environment and genetic traits of the cell," the abstract said. "Some DNA-damaging antibodies alone have little impact on normal cells, but in the presence of other conditions, such as pre-existing DNA-repair defects, can become highly toxic."
"These findings raise new questions about autoimmunity and DNA damage and reveal opportunities for new targeted therapies against malignancies particularly vulnerable to DNA damage," the article said.
Patrys was unchanged at 0.8 cents.

3D MEDICAL

3D Medical says that all resolutions relating to the merger with Mach7 Technologies and name change were passed overwhelmingly at its extraordinary general meeting.
3D said that pending formalities the merger was expected to be completed on April 7 2016 and the ASX code would change from 3DM to M7T.
The company said that former Alchemia director Ken Poutakidis had been appointed non-executive chairman with Albert Liong as managing-director and Damien Lim and Nobuhiko Ito as non-executive directors.
3D said that directors Frank Pertile and Stephen Hewitt-Dutton would retire with executive chairman Dr Nigel Finch remain as a non-executive director.
3D was up 0.1 cents or 1.7 percent to six cents.

BIOXYNE

Bioxyne says it will focus on the Lactobacillus fermentum PCC assets acquired in the merger of Probiomics and Hunter Immunology (BD: Oct 11, 2011; Apr 4, 2012).
Shortly after the merger Bioxyne fell 87.5 percent on news that the 320 patient, phase IIb trial of HI-164OV for chronic obstructive pulmonary disease exacerbations failed to meet the primary endpoint (BD: Jun 28, 2012).
The company sold the Hunter Immunology assets, but has continued to report revenue from the sale of its probiotic assets (BD: Sep 25, 2014; Sep 1, 2015).
Yesterday, Bioxyne released a corporate presentation yesterday and today said it had a plan and strategy to increase sales from its Lactobacillus fermentum PCC over the next 12 months.
PCC is the previous Probiomics code.
The company said that probiotics-based products was a high growth sector for the health and food supplements market.
Bioxyne said it would focus on lead asset Lactobacillus fermentum PCC a probiotic demonstrated to boost immune health as a result of its interaction with the gastrointestinal tract.
The company said it would launch two products in Australia in 2016, Progastrim and Protract for atopic dermatitis, both of which had Australian Therapeutic Goods Administration registration.
Bioxyne said it would undertake registration of PCC in China and initiate clinical studies to further support and boost the sales and marketing efforts of partners Nu-Skin and Christian Hansen, as well as develop new markets for PCC-based products, to be funded from existing cash reserves.
Bioxyne said that executive director Dr Peter French was responsible for the renewed focus and had “already achieved first steps for all of them”.
Bioxyne fell 0.1 cents or 4.55 percent to 2.1 cents.

ADHERIUM

Regal Funds Management has become a substantial shareholder in Adherium with 10,333,783 shares or 7.20 percent of the company.
The Sydney based Regal Funds said that it acquired 4,750,877 shares between December 15, 2015 and March 24, 2016 at prices ranging from 45 cents to 65 cents a share.
Adherium was unchanged at 50 cents.