Biotech Daily

Wednesday August 9, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: OSPREY UP 7%, USCOM DOWN 12%**

*** RESAPP FALLS 82% ON RESPIRATORY DIAGNOSIS FAIL**

*** PARADIGM DOSES 1st PATIENT IN PPS ROSS RIVER VIRUS TRIAL**

*** IMMURON READY FOR IMM-529 CLOSTRIDIUM DIFFICILE ISRAEL TRIAL**

*** STARPHARMA, MIPS $300k FEDERAL DENDRIMER GRANT**

*** USCOM DEVELOPS DIAGNOSTIC WIRELESS OPTIONS**

*** SIMAVITA DEVELOPING ALERTPLUS INCONTINENCE WARNING SYSTEM**

*** AUSCANN MEDICAL MARIJUANA MANUFACTURE, SUPPLY LICENCE**

*** CRESO: DR STU FILLMAN MEDICAL MANAGER, CANADA CEO WANTED**

*** LAGODA, FATIMA DICKEY, RICHARD BAYLES TAKE 11% OF CLINUVEL**

*** INVESTORS MUTUAL TAKES 7% OF MAYNE PHARMA**

MARKET REPORT

The Australian stock market was up 0.38 percent on Wednesday August 9, 2017 with the ASX200 up 21.9 points to 5,765.7 points. Seventeen of the Biotech Daily Top 40 stocks were up, 15 fell, seven traded unchanged and one was untraded.

Osprey was the best, up three cents or seven percent to 46 cents with 147,257 shares traded. Reva and Starpharma climbed six percent or more; Genetic Signatures, Orthocell and Psivida were up five percent or more; Admedus, Cellmid, Mesoblast and Prima improved four percent or more; Actinogen, Airxpanders, Bionomics, CSL, LBT, Pro Medicus and Viralytics rose more than one percent; Avita and Nanosonics were up more than one percent; with Cochlear and Medical Developments up by less than one percent.

Uscom led the falls, down two cents or 11.8 percent to 15 cents with 42,166 shares traded. Avita, Benitec and Sirtex lost more than three percent; Atcor, Clinuvel, Compumedics and Polynovo shed two percent or more; Acrux, Factor Therapeutics, Nanosonics, Neuren and Opthea were down more than one percent; with Ellex, Impedimed and Resmed down by less than one percent.

RESAPP HEALTH

Resapp fell as much as 82.3 percent on news that its 1,245-patient Smartcough-C trial failed to meet its endpoints for the accurate diagnosis of respiratory disease.

Resapp said that “contrary to instructions and training, a high number of patients were treated before clinical research staff recorded their cough sounds [and] a high number of recordings were also found to contain a second person’s cough sounds or an unacceptable amount of background noise and interference”.

In June, the company published very high accuracy data for the Resappdx mobile telephone application’s trial in Australian hospitals, claiming accuracy ranging from 70 percent to 97 percent in a 1,127 patient paediatric trial at the Perth, Western Australia-based Joondalup Health Campus and Princess Margaret Hospital (BD: Jun 22, 2017).

Last year, Resapp said that 524 subject results in a paediatric dataset improved its respiratory tract disease detection from 80 percent to 97 percent (BD: Mar 31, 2016).

Today, Resapp said that a preliminary analysis of the study data showed that “predefined endpoints for positive percent agreement and negative percent agreement with clinical diagnosis [were] unlikely to be met” for pneumonia, croup, upper respiratory tract infection, lower respiratory tract disease, asthma, reactive airways disease and bronchiolitis.

The company said that background noise and extraneous variables including respiratory illness treatment were “known to affect cough sound analysis and their presence has skewed these preliminary results”.

Resapp said that the co-primary endpoints of the study were the diagnosis of pneumonia compared to clinical and radiologic diagnosis, with secondary endpoints the diagnosis of upper respiratory tract infection, lower respiratory involvement, croup, asthma, reactive airways disease and bronchiolitis compared with a clinical diagnosis.

The company said that the predefined endpoints were based on achieving greater than 75 percent for positive percent agreement (PPA) and negative percent agreement (NPA).

Resapp said that for the 88 patients with pneumonia it achieved 47 percent PPA and 65 percent NPA on cough alone, increasing to 56 percent and 64 percent, respectively, with age, gender and symptoms added to the data.

The company said its best result was among 46 patients with bronchiolitis which saw 89 percent PPA and 84 percent NPA on cough alone, decreasing to 80 percent PPA and increasing to 95 percent NPA, respectively, with age, gender and symptoms added to the data.

Resapp chief executive officer Dr Tony Keating told Biotech Daily that with about $8 million in the bank and the trial costing between $2.5 million and $3 million, the company was ready to restart a new trial in November for the coming US Winter.

Dr Keating said that the Australian hospitals were more controlled environments compared to the three US hospitals which included Massachusetts general, the Cleveland Clinic and the Texas Children’s Hospital.

“We have enough money to run the study again,” Dr Keating said.

“We can refine the trial protocols and use the data generated from the trial to improve the robustness of the algorithm,” Dr Keating said.

Dr Keating said that the trial would take place at the same sites.

Resapp said that the Smartcough-C trial was a multi-site, double blind, prospective clinical study to investigate Resappdx for the diagnosis of respiratory disease in infants and children using cough sounds.

The company said that the study enrolled 1,245 patients aged 29 days to 12 years and used a range of smart phone models.

Resapp fell as much as 25.5 cents or 82.3 percent to 5.5 cents before closing down 24 cents or 77.4 percent at seven cents with 213.5 million shares traded.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has dosed the first of 24 patients in a phase II trial of pentosan polysulfate sodium (PPS) for Ross River virus, at Barwon Health in Geelong.
Paradigm said the randomized, double-blinded, placebo-controlled trial in Victoria and Queensland would evaluate patients with Ross River virus-induced arthralgia, or painful joints, for safety, tolerability and effects on symptoms, with results expected in mid-2018.
The company said that high rainfall and warm weather increased the incidence of Ross River virus in Victoria so far this year, resulting in an unusually high number of infections.
Paradigm said that 1,911 cases had been identified in the year to July 30, 2017, an 626.6 percent increase on the total of 263 cases for 2016.
Paradigm chief executive officer Paul Rennie said that new treatments were “desperately needed, especially in Victoria, where the rates of the disease have increased significantly, representing a large unmet medical need”.
Paradigm said the trial was the fourth active clinical trial since listing on the ASX.
The company has an ongoing 40-patient trial of the Zilosul formulation of pentosan polysulfate sodium for bone marrow oedema lesions, or bone bruising, at Melbourne’s Box Hill Sportsmed Biologic medical clinic (BD: Feb 23, 2016).
In June said its phase IIa trial of pentosan polysulfate sodium for allergic rhinitis, or hay fever, did not meet its primary endpoints of total nasal symptom score and peak nasal respiratory flow, blaming the formulation (BD: Jun 16, 2017).
Following the hay fever results, Paradigm said it would investigate the potential of pentosan polysulfate sodium for heart failure (BD: Jun 20, 2017).
Paradigm said that a phase I trial of pentosan polysulfate sodium for hay fever showed that it was safe and well-tolerated (BD: Aug 19, 2016).
Paradigm fell two cents or 6.25 percent to 30 cents.

IMMURON

Immuron says that Israel’s Ministry of Health and Hadassah Medical Centre have approved a 60-patient trial of IMM-529 for Clostridium difficile infection.
Immuron said that the trial would recruit diagnosed patients who had received standard of care antibiotic treatment, who would be randomized to either IMM-529 three times daily, or placebo, for 28 days.
The company said that the primary objective was to assess safety and tolerability, with secondary endpoints evaluating the preliminary efficacy of IMM-529 by duration and severity of symptoms and rate of disease recurrence.
Immuron said that the first-in-human trial at the Jerusalem-based Hadassah Medical Centre would begin “within the next few weeks”.
Immuron chief medical officer Dr Dan Peres said that IMM-529 “offers a novel and safe solution to a growing problem”.
Immuron said that Clostridium difficile infection was “a major-medical problem causing an estimated annual economic burden of more than $US10 billion globally”.
The company said that the problem was “especially acute in hospitals and in long-term in-patient care facilities due to bacteria produce toxins causing inflammation of the colon resulting in severe diarrhoea and, in severe cases, death”.
Immuron said that about 28,000 patients died each year from Clostridium difficile infection in the US alone, while recurrent infections affected about 100,000 people in the US each year.
Immuron fell half a cent or 2.8 percent to 17.5 cents.

STARPHARMA, MONASH INSTITUTE OF PHARMACEUTICAL SCIENCES

Starpharma says that with the Monash Institute of Pharmaceutical Sciences it has won a $300,000 Federal Government grant to expand its dendrimer technology.
Starpharma said the Science and Industry Endowment Fund business fellowship program grant came under the science, technology engineering and mathematics plus (STEM+) program linking research to business and would fund two post-doctoral research fellows.
The company said that the funding would support Starpharma and the Institute “to further advance collaborative programs” using the company’s targeted dendrimer enhanced product (DEP) technology, which used conjugates to enhance drug concentration at the disease site and reduce off-target toxicity to improve therapeutic outcomes for patients.
Starpharma chief executive officer Dr Jackie Fairley said the collaboration would “expand the activities around our novel targeted DEP conjugates and is expected to generate exciting technical results and considerable commercial benefits by way of new intellectual property and commercialization opportunities for Starpharma”.
Starpharma climbed five cents or six percent to 88.5 cents with 1.4 million shares traded.

USCOM

Uscom says it has developed wireless connectivity to remote digital medical record systems for its Uscom 1A ultra-sonic cardiac output monitor.
Uscom said the development included software and hardware to allow wireless connectivity to remote systems and telemetric transfer of medical examination data.
The company said that in the US, China and much of Asia, the connectivity option was a pre-requisite for tendering for medical device contracts and its Spriosonic and BP+ products also supported digital connectivity to medical record systems.
Uscom executive chairman Prof Rob Phillips said his company was “establishing itself as a digital medical device specialist”.
Uscom fell two cents or 11.8 percent to 15 cents.

SIMAVITA

Simavita says it has begun manufacturing of its low-cost, Alertplus smart incontinence management (SIM) system for adult and child nappies.
Simavita said that patents had been granted for the Alertplus system in all major markets and Alertplus had been manufactured in low volume through a manufacturing partner, with discussions underway with a number of manufacturers.
The company said that a mobile telephone application was available with the Alertplus sensor which informed carers when to change the nappy, and a low cost data capture device had been developed.
Simavita said its Assessplus and SIM system revenues were increasing across all markets, and “many existing SIM users have converted to Assessplus”.
The company said it had a three-year distribution agreement with nteh Stockholm, Sweden-based Onemed A/S covering The Netherlands and Nordic countries and would replace Abena as its representative in Denmark.
Simavita said it had made “substantial headway in identifying distribution partners in both the UK and Spanish markets”.
The company said that in North American it had “altered our relationship with Medline to that of non-exclusive distribution … [and it maintained] a close and ongoing working relationship with Medline and continue to explore new opportunities”.
Simavita was untraded at 3.7 cents.

AUSCANN GROUP HOLDINGS

Auscann says it has been granted an Australian manufacturing licence authorizing the manufacture and supply of medicinal cannabis under the Narcotic Drugs Act 1967.
Auscann said that the Federal Office of Drug Control granted the Licence which enabled the manufacture and supply of cannabinoid medicines.
The company said it was one of a few companies that could cultivate, manufacture and supply Australian-produced cannabinoid medicines to patients.
Auscann said the licence followed cultivation licences in Western Australia and in Tasmania through a partnership with Tasmanian Alkaloids (BD: May 5, July 11, 2017).
The company said that Tasmanian Alkaloids was awaiting the outcome of a further manufacturing licence application for the proposed operations in Tasmania.
Auscann said that the manufacturing licence positioned it as “one of the first complete and fully Australian supply chains to provide medicinal cannabis products to patients”.
Auscann managing-director Elaine Darby said that the company aimed to “provide high quality, cost effective cannabinoid medicines for Australian patients”.
“Securing both a cultivation and a manufacturing licence will enable us to achieve this aim and demonstrates our leadership position in the industry,” Ms Darby said.
Auscann was up 13.5 cents or 29.4 percent to 59.5 cents with 10.95 million shares traded.

CRESO PHARMA

Creso says that it has appointed Dr Stu Fillman as its Australian medical manager and is looking for a Canadian chief executive officer.
Last month, Creso said it would acquire the Nova Scotia, Canada-based medicinal cannabis producer Mernova Medicinal for $C10.1 million ($A10.1 million) in cash and equity to integrate its supply and production chain by building its own growing and extraction facilities (BD: Jul 27, 2017).
Today, the company said that it had established a Canadian executive team comprising chief executive officer Dr Miriam Halperin Wernli, chief operating officer, David Russell; director Adam Blumenthal and Mernova chief executive officer Bill Fleming.
Creso said that co-founder and chairman Boaz Wachtel would move to non-executive chairman.
The company said that the Canada chief executive officer would be responsible for overseeing Canadian operations and Creso’s planned good manufacturing process cultivation facility and its carbon dioxide extraction facility, as well as the development and manufacture of medicinal cannabis products for Canada.
Creso said its executives would conduct a due diligence trip to Canada over the next few weeks, visiting the Mernova site ahead of Mernova’s plans to construct a 20,000 square foot (1,858 square metres) medicinal cannabis growing facility and establishing the Creso Canada subsidiary.
The company said Dr Fillman would be “responsible for driving commercial partnerships with pharmaceutical companies as well as overseeing medicinal cannabis in Australia and supporting the company’s planned clinical trials in animal and human health”.
Creso said that Dr Fillman had more than 10 years academic and commercial experience in neuroscience and psychiatry and most recently, was Sanofi Genzyme’s national screening manager for rare diseases.
The company said that Dr Fillman held a Bachelor of Science and from the University of Guelph, Ontario, a Master’s of Science from McMaster University, Ontario and a Doctorate of Philosophy in psychiatry from the University of New South Wales.
Creso was up one cent or two percent to 50 cents.

CLINUVEL

Lagoda Investment Manager, Fatima Dickey and Richard Bayles have increased their holding in Clinuvel from 4,720,236 shares (10.03%) to 5,255,680 (11.01%).
The New York-based Lagoda said it bought and sold shares on-market between April 7, 2016 and August 7, 2017 at prices ranging from $5.20 to $8.68.
Clinuvel fell 13 cents or two percent to $6.40.

MAYNE PHARMA

The Sydney-based Investors Mutual says it has increased its substantial holding in Mayne Pharma from 94,494,139 shares (6.25%) to 113,984,705 shares (7.44%).
Investors Mutual previously said that it held the shares along with Aurora Investment Management which owned 20 percent of Investors Mutual and Pacific Current Group which owned 100 percent of Aurora Investment Management (BD: May 4, 2017).
The company said that registered holders included Sandhurst Trustees, Citicorp Nominees, JP Morgan State Super, State Street and RBC Global Services Australia.
Investors Mutual said it bought and sold shares between May 30 and August 4, 2017 with the single largest purchase on June 21, of 1,687,457 shares for $1,746,349 or $1.035 a share.
Mayne fell six cents or 7.45 percent to 74.5 cents with 56.2 million shares traded.