# Biotech Daily

Monday August 4, 2014

*Daily news on ASX-listed biotechnology companies*

*** ASX, BIOTECH DOWN: PRIMA UP 8%, IDT DOWN 12.5%**

*** BIOTA'S LANI 'FLU DRUG 'NO SIGNIFICANT BENEFIT OVER PLACEBO'**

*** NEW INDICATIONS FOR OSPREY AVERT DYE REDUCTION SYSTEM**

*** BIO-MELBOURNE HOSTS DR THOMAS LÖNNGREN ON EU REGULATION**

*** PHARMAXIS SUES FINANCIER NOVAQUEST**

*** UNILIFE 'COMPLETES' EQUITY DRAW-DOWN FACILITY**

*** BENNELONG 'REVISES' RESMED SUBSTANTIAL CALCULATION TO 2.7%**

*** MEDICAL AUSTRALIA APPOINTS DR AMY CROUCH VET MANAGER**

## MARKET REPORT

The Australian stock market fell 0.28 percent on Monday August 4, 2014 with the S&P ASX 200 down 15.5 points to 5,540.9 points.

Nine of the Biotech Daily Top 40 stocks were up, 19 fell, six traded unchanged and six were untraded.

Prima was the best, up 0.3 cents or 7.7 percent to 4.2 cents with 1.6 million shares traded.

Clinuvel climbed seven percent to $2.30; Neuren was up five percent; Biotron rose 4.35 percent; both Patrys and Viralytics were up 3.7 percent; Analytica and Osprey rose two percent or more; Impedimed and Resmed were up one percent or more.

IDT led the falls, down 3.5 cents or 12.5 percent to 24.5 cents with 21,341 shares traded.

Oncosil lost eight percent; Acrux fell 5.4 percent; Medical Developments, Mesoblast and Prana fell four percent or more; Alchemia, Anteo, Genetic Technologies, Pharmaxis and Tissue Therapies were down more than three percent; Bionomics shed two percent; Benitec, Cochlear, Ellex, GI Dynamics, Nanosonics, Phosphagenics and Sirtex lost one percent or more; with CSL and Starpharma down by less than one percent.

## BIOTA PHARMACEUTICALS

Biota says that top-line data from its phase II 'Igloo' trial comparing 40mg and 80mg laninamivir octanoate to placebo shows no significant benefit.

Biota said that the 639-patient, randomized, double-blind, placebo-controlled, parallel-arm trial found that median time to alleviation of influenza symptoms was 102.3 hours for the 40mg cohort, 103.2 hours for the 80mg cohort and 104.1 hours for the placebo cohort.

The company said the median time to alleviation of influenza symptoms was the trial's primary endpoint and neither the 40mg nor the 80mg cohort achieved a statistically significant reduction in the time to symptom alleviation compared to placebo ($p = 0.248$ and $p = 0.776$, respectively).

Biota said that 248 patients had polymerase chain reaction (PCR) confirmed influenza A or B virus and were included in the intent-to-treat efficacy analyses.

The company said that about 75 percent and 19 percent of the influenza-confirmed patients were infected with influenza A H1N1 2009 and H3N2, respectively, with six percent infected with influenza B.

Biota said that patients in both the 40mg ($p < 0.001$) and 80mg ($p = 0.070$) cohorts demonstrated a statistically significant reduction in viral shedding on day-3 of the study compared to placebo as quantified by quantitative reverse transcription polymerase chain reaction (qRT-PCR) and a statistically significant proportion of patients in both the 40mg ($p = 0.002$) and 80mg ($p = 0.020$) cohorts were culture negative on day-3 of the study as compared to placebo.

Biota said that influenza-infected patients in the 40mg cohort had a statistically significant reduction in the incidence of secondary bacterial infections compared to placebo ($p = 0.013$) and the nature and extent of adverse events were similar in the three cohorts, with the incidence of serious adverse events low and balanced across the three cohorts.

Biota chief executive officer Russell Plumb said it was "disappointing that the rapid and significant onset of antiviral activity against the influenza virus that the two treatment arms demonstrated with Lani did not translate into a meaningful reduction in the time to alleviate patient-reported influenza symptoms".

"We expect to complete a full analysis of additional clinical, safety, and pharmacokinetic data forthcoming from this trial over the next several months, however, at this time we do not have any plans to independently advance the development of Lani for the treatment of influenza and intend to evaluate next steps for the Lani program outside of Japan with our partner, Daiichi Sankyo," Mr Plumb said.

Biota said it intended to provide a detailed update on the efficacy and safety results of the trial, the status of the program and its corporate strategy in September 2014.

In June, following the termination of its $US231 million 2011 Biomedical Advanced Research and Development Authority (BARDA) contract, Biota said it would close its Australian operations and sack more staff (BD: Jun 3, 2014).

Biota was developing its long-acting neuraminidase inhibitor laninamivir octanoate, when it merged with Nabi Pharmaceuticals to access its $US54 million in cash, eventually settling for $US27 million in cash (BD: Apr 1, 2011; Apr 23, Oct 30, 2012).

In April 2014, BARDA halted work on the contract and terminated it in May, refuting the company's claims that it had not been given reasons either for the stop-work order or the termination (BD: Apr 30, May 1, 9, 2014).

Last year, Biota sacked 30 percent of its workforce and closed its pre-clinical antibiotic programs (BD: Apr 17, Nov 22, 2014).

On the Nasdaq on Friday, August 1, Biota fell 79 US cents or 24.61 percent to $US2.42 ($A2.60 - equivalent to 32.5 cents prior to the Nabi merger, when it was trading around $A1.00), with 1.6 million shares traded.

## OSPREY MEDICAL

Osprey says that US doctors have helped it identify peripheral artery disease imaging as a potential new market for its Avert dye reduction system.

Osprey said that lower extremity peripheral artery disease was a common problem caused by the narrowing or blockage of vessels that carried blood to the legs and could result in severe pain and led to life-threatening limb amputation if not diagnosed and treated.

The company said that common treatments involved opening narrowed or blocked arteries with balloon catheters and stents guided by X-ray imaging using contrast dye which was potentially harmful to the kidneys, causing contrast-induced nephropathy.

Osprey said that US physicians using Avert for cardiac procedures identified an opportunity to use the system to control the infusion of dye for patients being treated for peripheral artery disease.

The company said that since the launch of Avert in Texas, there had been significant use in peripheral artery disease procedures with good success.

Osprey chief executive officer Mike McCormick said that just as the Avert system could help minimize contrast dye used in coronary heart procedures it could also help patients having dye injected while undergoing treatment for peripheral artery disease.

“Application of the Avert system for [peripheral artery disease] was led by physicians who are already using it for heart procedures and see its potential for use in a wider range of situations that involve the use of contrast dye,” Mr McCormick said.

Osprey said that there were about 950,000 lower extremity peripheral artery disease interventional procedures in Western Europe and the US each year, with about half of all patients undergoing a peripheral interventional procedure at risk of acquiring contrast-induced nephropathy due to accompanying factors such as diabetes or chronic kidney disease.

The company said that there was an addressable market opportunity of 475,000 peripheral artery disease procedures a year and $US200 million in potential revenue, with the number of procedures expected to grow due to the high prevalence of diabetes in the Western world, an ageing population, and that peripheral artery disease was under-diagnosed and treated.

Separately, Osprey has been developing a limb recovery system and in April reported that a 20-patient pilot study achieved significant reductions in bacterial levels in diabetes patients with life or limb-threatening foot infections (BD: Oct 22, 2013; Apr 10, 2014).

Osprey was up one cent or two percent to 51 cents.

## BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says that former European Medicines Agency executive director Dr Thomas Lönngren will discuss regulation at a briefing on August 13, 2014.

Bio-Melbourne Network chief executive officer Dr Krystal Evans said that Dr Lönngren was the EMA executive director from 2001 to 2010 and was “a highly-respected and sought-after expert in European pharmaceutical regulatory approvals”.

The Network said that Dr Lönngren would discuss experience gained from working at the EMA and provide advice on navigating through regulatory uncertainties, as well as share his opinions on the future regulations in Europe in drug development and the emergence of pharmaceutical company mobile telephone medical applications.

The August 13 Bio-Briefing will be held at Piper Alderman, 385 Bourke Street, Melbourne. Registration is from 4pm for a presentation from 4:15pm to 5:30pm followed by networking drinks.

For more information and to register go to: http://www.biomelbourne.org/events/view/329.

## PHARMAXIS

Pharmaxis says that it has filed a lawsuit against Novaquest Pharma Opportunities Fund III LP following an attempt by Novaquest to back out of its funding obligations.

Last month, Pharmaxis said that Novaquest's attempt to withdraw from $US20 million in agreed payments could impact its impending US phase III trial of Bronchitol for cystic fibrosis (BD: Jul 8, 2014).

Pharmaxis said at that time that Novaquest alleged on July 4, 2014 that Pharmaxis had breached the January 30, 2013 financing agreement and "an event of default will occur on August 3, 2014".

The company said in July that Novaquest alleged that it had not worked in a commercially reasonable manner to obtain reimbursement status for Bronchitol from key European governmental and non-governmental payers, but did not provide any detail to support the allegation of a breach of the agreement and Novaquest had failed to raise the matter through the dispute resolution required by the agreement.

Pharmaxis said it "strongly rejects the allegation it is in breach, will contest the allegation and take all appropriate steps to ensure that Novaquest complies fully with its obligations under the financing agreement.

Today, Pharmaxis said the lawsuit was filed in the Supreme Court of the State of New York, alleging that Novaquest had breached the agreement by repudiating its funding obligations and failing to comply with communication and dispute resolution provisions.

Pharmaxis said that Novaquest had not acted in good faith and had interfered with Pharmaxis' negotiations with potential commercial partners for Bronchitol.

Pharmaxis said it was seeking injunctive relief preventing Novaquest from suspending or terminating its obligations to provide a further $US20 million, a declaration from the court that Pharmaxis did not breach the agreement and compensatory and punitive damages.

Pharmaxis chief executive officer Gary Phillips said the proceedings were launched "to protect Pharmaxis' interests".

"We believe that the initial notice from Novaquest was deliberately timed to gain maximum leverage for Novaquest to force a renegotiated agreement," Mr Phillips said.

"The company is committed to asserting its clear rights to the additional funding agreed to by Novaquest under the financing agreement," Mr Phillips said.

"Notwithstanding the lawsuit, we remain open to a commercial resolution with Novaquest," Mr Phillips said. "We are also pursuing negotiations with a potential commercial partner for Bronchitol in the US to attempt to secure alternative funding for the CF303 clinical trial."

"That trial is a critical step to [US Food and Drug Administration] approval and subsequent access to the valuable US cystic fibrosis market and brings a much needed new treatment option to US [cystic fibrosis] patients," Mr Phillips said.

Pharmaxis fell 0.2 cents or 3.3 percent to 5.8 cents with one million shares traded.

## UNILIFE CORP

Unilife says it has "completed" its at-the-market equity draw-down facility with Cantor Fitzgerald issuing 5,811,800 shares of US common stock for $US12.4 million.

The company said that the majority of issued shares were acquired by "a group of large US institutional investors".

Last week, Unilife said its net operating cash burn for the three months to June 30, 2014 was $US20,009,000 ($A21,478,380) with cash at the end of the quarter of $US10,838,000, it had the $US12.8 million facility and had increased expenditure ahead of an expected increase in cash receipts and revenue in 2014-'15 (B: Jul 31, 2014).

Unilife fell 5.5 cents or 11.3 percent to 43 cents with 1.4 million shares traded.

## RESMED

Bennelong Funds Management Group says it has ceased its substantial shareholding in Resmed through a “revision of calculation”.

In July, the Queen Street, Melbourne-based Bennelong Funds said it had become a substantial shareholder in Resmed with the acquisition of 38,056,531 shares (5.0393%) (BD: Jul 10, 2014).

Resmed’s most recent Appendix 3B New Issue announcement on May 21, 2014 said the company had 1,402,915,440 Chess depositary interests on issue, meaning that Bennelong held 2.7 percent of the company.

Bennelong said the shares were held by BNP, NAB Asset Servicing, UBS. JP Morgan and HSBC.

Resmed was up five cents or 0.96 percent to $5.28 with 11.2 million shares traded.

## MEDICAL AUSTRALIA

Medical Australia says it has appointed Dr Amy Crouch as its national veterinary account manager, effective from June 2, 2014.

Medical Australia said that Dr Crouch would lead the sales and marketing team in the animal healthcare division.

The company said that Dr Crouch would promote the range of proprietary regenerative stem cell, platelet-rich plasma and nanofibre technologies that it owned or was licenced to distribute in Australia to the animal healthcare industry.

Medical Australia said Dr Crouch would educate veterinarians and their support workers about the technologies as animal treatments.

The company said that Dr Crouch had worked as a veterinarian and undertaken research work.

Medical Australia said that Dr Crouch held a Bachelor of Veterinary Science and a Bachelor of Science University of Queensland, along with post-graduate qualifications in healthcare and management.

Medical Australia was untraded at 16 cents.