# Biotech Daily

Tuesday October 21, 2014

*Daily news on ASX-listed biotechnology companies*

*** ASX UP, BIOTECH DOWN: GENETIC TECH UP 13%, ANALYTICA DOWN 11%**

*** HATCHTECH PHASE II TRIAL KILLS 100% OF HEAD LICE EGGS**

*** PHARMAUST'S FIRST CANCER PATIENT DIES, PPL-1 TRIAL DELAY**

*** CLINICAL GENOMICS, CSIRO BOWEL CANCER BLOOD TEST AGREEMENT**

*** CIRCADIAN 1.5m CEO DR MEGAN BALDWIN OPTIONS, PLANS AGM**

*** BLUECHIIP LOSES 2nd CEO DR JASON CHAFFEY, JAPAN CONTRACT**

*** DR TRACEY MYNOTT, MYENG TAKE 15% OF ANATARA**

*** AUSBIOTECH'S DR ANNA LAVELLE ELECTED ATSE FELLOWSHIP**

## MARKET REPORT

The Australian stock market edged up 0.11 percent on Tuesday October 21, 2014 with the S&P ASX 200 up 5.6 points to 5,325.0 points.

Twelve of the Biotech Daily Top 40 stocks were up, 18 fell, seven traded unchanged and three were untraded.

Genetic Technologies was the best for the second trading day in a row, up 0.2 cents or 13.3 percent to 1.7 cents with 533,363 shares traded, followed by Living Cell up 13.1 percent to 6.9 cents with 511,184 shares traded.

Benitec, IDT and Patrys climbed five percent or more; Oncosil and Uscom were up four percent or more; Cochlear, Impedimed, Nanosonics, Resmed and Tissue Therapies were up more than one percent; with Acrux and Sirtex up by less than one percent.

Analytica led the falls, down 0.4 cents or 11.1 percent to 3.2 cents with 4.0 million shares traded, followed by GI Dynamics down 10.7 percent to 25 cents with 1.2 million shares traded and Anteo down 10 percent to 13.5 cents with four million shares traded.

Cellmid fell 7.4 percent; Clinuvel, Ellex and Prana lost more than six percent; Osprey fell 5.2 percent; Antisense, Atcor and Pharmaxis fell were down four percent or more; Alchemia, Avita and Mesoblast were down three percent or more; Medical Developments and Viralytics shed more than one percent; with Bionomics, CSL and Starpharma down by less than one percent.

## HATCHTECH

Hatchtech says that a phase II clinical study shows that a single, 10-minute application of its Xeglyze head lice and egg treatment has 100 percent ovicidal efficacy.

Hatchtech said that the Melbourne-based, 50-subject, double-blind, randomized, vehicle-controlled, parallel-group study in subjects with an active head lice infestation aged three years and above evaluated the ovicidal efficacy, or ability to kill lice eggs, of a single, 10-minute application of Xeglyze lotion.

The company said that study compared the ovicidal efficacy of Xeglyze lotion 0.74 percent compared to a vehicle control, with a minimum of five eggs per subject collected pre-and immediately post treatment and then eggs were then incubated for 14 days.

The study endpoint measured the proportion of eggs that hatched pre-treatment relative to the proportion of hatched eggs post treatment and Xeglyze demonstrated 100 percent ovicidal efficacy, with the hatch rate reduced from 93.3 percent pre-treatment to zero percent, post treatment, compared to a vehicle lotion, which reduced the hatch rate from 79.5 percent to 36.0 percent ($p < 0.0001$).

Hatchtech said the study confirmed previous in-vitro studies using eggs sampled from a laboratory maintained head lice colony, in which eggs were treated with Xeglyze, a vehicle lotion, a water control and the commercially available over-the-counter Nix containing one percent permethrin as the active ingredient.

The company said that the eggs were incubated for 14 days and observed for hatchability, with none of the eggs exposed to Xeglyze hatching, compared to 56 percent for vehicle, 59 percent for Nix, and 87 percent exposed to water.

In September, Hatchtech said that its two US pivotal phase III trials of Xeglyze showed that it killed lice and their eggs in single 10-minute treatment (BD: Sep 2, 2014).

Hatchtech said at that time that 704 subjects with active head lice infestation aged six months and older were enrolled at 14 study sites in the double-blind, randomized, multi-center, vehicle-controlled, parallel-group and treated subjects

The company said that the US Food and Drug Administration special protocol assessment agreement trials showed that 81.5 percent of patients who received one application of Xeglyze and without nit-combing remained lice-free at all follow up visits through to the day 14 visit, the primary efficacy endpoint.

Today, Hatchtech chief executive officer Hugh Alsop told Biotech Daily that the phase II Melbourne trial ”proves definitively that Xeglyze kills the eggs”.

“The phase III trial proved that we eradicated a head lice infestation of lice and eggs, but did not specifically look at the killing of tracked individual eggs,” Mr Alsop said.

Mr Alsop said that the phase II Melbourne study results, combined with the results using eggs collected from the laboratory maintained colony, “clearly confirm the potent ovicidal efficacy of Xeglyze lotion”.

“One hundred percent of eggs that come into contact with Xeglyze are killed,” Mr Alsop said.

“Hatchtech has now completed clinical development of Xeglyze lotion, producing exceptional efficacy data against both lice and their eggs that validates the unique benefit of Xeglyze lotion for the treatment of a head lice infestation,” Mr Alsop said.

“We hope to have a pre-new drug application meeting with the FDA early next year and then file the application by July 2015,” Mr Alsop said.

“Following the 10-month FDA review and, if successful, Xeglyze should be on the market in 2016,” Mr Alsop said.

Hatchtech said that approved products on the market had little or no efficacy against eggs and if the eggs were not physically removed, an infestation would quickly return.

Hatchtech is a private company.

## PHARMAUST

Pharmaust says that the first patient in its trial of PPL-1 for cancer has died and it will resubmit the ethics application to the Royal Adelaide Hospital.

Pharmaust said that the patient died “due to reasons unrelated to the study drug and this has understandably resulted in a standard process of investigations resulting in delays in the treatment of the second patient”.

The company said that PPL-1 was an approved drug launched by an animal health corporation for the treatment of parasitic diseases in animals.

Pharmaust said its wholly-owned subsidiary Pitney Pharmaceuticals owned patents on the use of PPL-1 in cancer and malignant disease.

Pharmaust executive chairman Dr Roger Aston said it was “sad and unfortunate that the first patient passed away in days after beginning treatment with PPL-1”.

“It should be noted that an inclusion criterion of the trial is that patients will have failed all other standards-of-care, [and] as such, some of the patients entering the trial may have significant progressive disease,” Dr Aston said.

Dr Aston said that PPL-1 would be potentially administered to patients suffering from diverse cancers, including lung, pancreas, oesophageal, gastric, colorectal, ovarian, breast, prostate, liver, sarcoma, lymphoma and melanoma.

Pharmaust fell 0.1 cents or 10 percent to 0.9 cents with 22.4 million shares traded.

## CLINICAL GENOMICS, CSIRO

Clinical Genomics says it has signed an agreement with the Commonwealth Scientific and Industrial Research Organisation for biomarkers for colorectal cancer.

Clinical Genomics said the biomarkers were jointly discovered with CSIRO and the agreement would allow it to develop, deliver and promote its Colovantage Plasma blood test for bowel cancer.

Clinical Genomics chief executive officer Dr Larry LaPointe said that the “collaborative research milestone with CSIRO ... [would] make a contribution to bowel cancer screening”.

Dr LaPoint said that a pilot program of the blood test had been conducted in New South Wales and the clinical testing around the patent-pending technology was encouraging.

CSIRO head of colorectal cancer research Dr Trevor Lockett said that Australia had one of the world’s highest rates of bowel cancer, with more than 12,500 men and women diagnosed every year and about 80 Australians dying from it each week.

“The genes we’ve identified with cancer-specific signatures can be detected in the blood of many patients with early stages of bowel cancer,” Dr Lockett said.

“Thanks to our collaboration with Clinical Genomics, these sensitive and accurate biomarkers can now be used for the early detection of cancer,” Dr Lockett said.

“We hope to dramatically increase survival rates for those cancer-carrying subjects who have chosen not to use the current bowel screening standard, the faecal occult blood test, and might otherwise have gone untested and undetected,” Dr Lockett said.

“Our ultimate aim is to integrate this blood test into protocols for bowel cancer screening around the world and thus to save many thousands of lives in the future,” Dr LaPointe said.

Clinical Genomics is a private company.

## CIRCADIAN TECHNOLOGIES

Circadian will vote to issue chief executive officer Dr Megan Baldwin 1,500,000 options as well as 1,000,000 options to Bell Potter for corporate advisory services.
Circadian said that Dr Baldwin's options would be issued "for no cash consideration and with a zero exercise price" vesting in six months of granting and exercisable within three years of vesting.
The company said that the Bell Potter options would be exercisable at 26.25 cents a share between one and three years from grant.
The Circadian notice of meeting said it would seek shareholder approval for the issue of up to 73,142,857 placement shares and 40,000,000 options as well as the ratification of the issue of 6,857,143 shares to DWS Investments.
The company also proposed a long term incentive plan and a non-executive director share and option plan.
Circadian said shareholders would vote on the election of directors Russell Howard and Tina McMeckan.
The meeting will be held at Computershare Conference Centre, Yarra Falls, 452 Johnston Street, Abbotsford, Melbourne, on November 18, 2014 at 11am (AEDT).
Circadian was unchanged at 17 cents.

## BLUECHIIP

Bluechiip says that managing director and chief executive officer Dr Jason Chaffey will resign by the end of 2014, the second chief executive officer to depart this year.
In January the then chief executive officer Brett Schwarz resigned and the then chief technical officer Dr Chaffey was promoted (BD: Jan 28, 2014).
Today, Bluechiip quoted Dr Chaffey saying that "the role of managing director involving primarily licencing and commercialization of the technology is more suitable to a person with these skill sets".
The company said that Dr Chaffey would be available to assist until the end of the year and in all the licencing and business development activities currently in progress.
Bluechiip said it had senior staff managing sales, manufacturing and development and had appointed Thomas Tay who secured the distribution agreement with the Tokyo, Japan-based NPO Bio Bank Support Organisation (see below).
The company said that Dr Ian Johnston would continue providing technological leadership and it had begun a search for a new managing director
The company said it had an exclusive distribution agreement with Tokyo's NPO Bio Bank to sell the product range in Japan for bio-banking and other life science related markets, including minimum ordering obligations with annual purchases of about $300,000.
Bluechiip said that NPO Bio Bank was established to improve operations of sample management in bio-banks and to provide consultation to bio-banks regarding sample management technologies and equipment to ensure quality of storage and research based on market and industrial knowledge.
The company said that following validation of the dual identity vial by the Netherlands-based Micronic and completing the first prototype of the multivial reader, both companies agreed to launch the system at the Society for Laboratory Automation and Screening conference in Washington, DC, in February 2015.
Bluechiip said that Micronic would produce a small volume of dual identity vials for market testing and sample product for selected customers.
Bluechiip was unchanged at 8.2 cents with 1.15 million shares traded.

## ANATARA LIFESCIENCES

The Queensland-based Myeng Pty Ltd says it holds 5,002,635 shares or 14.55 percent of Anatara.

In a substantial shareholder notice, Anatara chief science officer Dr Tracey Mynott said that the shares were acquired between July 15, 2010 and April 30, 2013 for $500, or 0.01 cents a share.

Dr Mynott told Biotech Daily that most of the shares were issued in lieu of payment for her work as well as the intellectual property she created relating to the use of the pineapple stem-based bromelain technology (BD: Oct 16, 2014).

Anatara was up 0.5 cents or 1.3 percent to 39 cents.

## AUSBIOTECH

Ausbiotech says that chief executive officer Dr Anna Lavelle has been elected to the Fellowship of the Australian Academy of Technological Sciences and Engineering.

Ausbiotech said that the Academy was an independent body of 800 scientists and engineers “seeking to enhance Australia’s prosperity through technological innovation.”

The industry organization said that Dr Lavelle was among businesspeople, academics, innovators and public sector figures elected to the Academy, including chief scientist, Prof Ian Chubb.

Ausbiotech said that Dr Lavelle was one of four Victorians and eight women elected to the Academy.