

Biotech Daily

Tuesday April 16, 2013

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: GENETIC TECH UP 21%, CLINUVEL DOWN 12%
- * UCSD JOINS BENITEC PHASE I/II TT-034 HEPATITIS C STUDY
- * GENETIC TECHNOLOGIES JUMPS ON MARCH STUDY RESULTS
- * IDT REVISES GUIDANCE FROM POSITIVE TO FLAT
- * PROGEN UNDERWRITTEN RIGHTS OFFER FOR \$5.2m
- * SUDA ARTIMIST MANUFACTURING SCALE-UP COMPLETED
- * NEURODISCOVERY ACQUIRES ENIGMA, NAME CHANGE TO ONCOSIL
- * UNIVERSITY OF SYDNEY HOSTS 1st TEDMED CONFERENCE

MARKET REPORT

The Australian stock market fell 0.34 percent on Tuesday April 16, 2013 with the S&P ASX 200 down 17.1 points to 4,950.8 points.

Six of the Biotech Daily Top 40 stocks were up, 22 fell, six traded unchanged and six were untraded.

Genetic Technologies was the best, up 1.5 cents or 20.55 percent to 8.8 cents with 642,444 shares traded.

Medical Developments climbed 4.3 percent; Bionomics, Nanosonics and Sirtex were up more than one percent; with Acrux and CSL up by less than one percent.

Clinuvel led the falls, down 26 cents or 12.3 percent to \$1.85, with 14,802 shares traded, followed by Pharmaxis down 12.3 percent to 28.5 cents with 1.9 million shares traded and Ellex down 10.3 percent to 17.5 cents with 100,000 shares traded.

Osprey lost 9.3 percent; Benitec was down 7.1 percent; Psivida was down 5.5 percent; Avita and Phylogica fell more than four percent; Allied Health, Cellmid, Neuren, Phosphagenics and Tissue Therapies were down more than three percent; Prana, Prima and QRX shed more than two percent; Alchemia, Atcor, Mesoblast, Resmed, Starpharma and Viralytics were down more than one percent; with Cochlear and GI Dynamics down by less than one percent.

BENITEC BIOPHARMA

Benitec says the University of California, San Diego Health Sciences is the second site in its phase I/II trial of TT-034 for hepatitis C virus, with Duke Clinical Research Unit the first. The company said that University of California, San Diego (UCSD) professor of medicine Prof David Wyles would be the principal investigator for the study, with UCSD Health Sciences Prof Robert Gish a consultant and sub-principal investigator for the study. "This is the first time that this therapeutic modality is being tested in humans and if it is successful I believe it can be a significant step forward, not only for [hepatitis C] treatment but potentially also as a treatment modality for hepatitis B," Dr Gish said.

Benitec chief executive officer Dr Peter French said that "having our two clinical centers in place moves us a step closer to initiating the phase I/II clinical trial, which we expect to occur during the second half of 2013".

The company said the 14-patient trial would be an open-label, dose-escalation study to evaluate the safety and activity of single doses of TT-034 in patients with chronic hepatitis C genotype 1 infection who had failed previous treatments.

Benitec said that additional cohorts might be added during the study to confirm the results of the trial.

The company said that the primary safety endpoints were dose limiting adverse events, with primary end points of serum viral load reduction and degree of hepatocyte transduction, measured through liver biopsies.

Benitec said the trial protocol included a pre-specified interim read on safety and activity within months of trial commencement.

Benitec fell 0.1 cents or 7.1 percent to 1.3 cents.

GENETIC TECHNOLOGIES

A Genetic Technologies media release in the US, reporting a March presentation of a study of its Brevagen test, appears to have sparked strong trading in its US shares. Last night on the Nasdaq, Genetic Technologies (GENE) climbed 51 US cents or 22.8 percent to \$US2.75 (\$A2.65) with 1,804,793 common shares traded.

Each US share is equivalent to 30 Australian shares.

The Genetic Technologies' media release said that a study of its Brevagen breast cancer diagnostic in 197 women, entitled 'Impact of Genomics on the Assessment and Management of Breast Cancer Risk in a Woman's Healthcare Clinic' had been presented at the National Interdisciplinary Breast Center Conference in Las Vegas, Nevada from March 23 to 27, 2013.

Genetic Technologies said that the study, performed at the Personalized Women's Healthcare in Plano, Texas found that Brevagen "more accurately identifies a woman's chances of getting breast cancer than the Breast Cancer Risk Assessment Tool alone, leading to increased patient compliance with performing regular self breast exams and annual screenings".

Personalized Women's Healthcare physician Dr Eric Jacoby said the practice had been using the Brevagen test for more than a year.

"It has helped us to make more informed decisions in how we monitor our patients who are at risk and develop personalized breast health plans," Dr Jacoby said.

"We are pleased that the results of our report clearly demonstrate that genetic information provided by the Brevagen test show significant reductions in the five year and lifetime intermediate risk groups, 35 percent and 23 percent respectively," Dr Jacoby said. On the ASX, Genetic Technologies was up 1.5 cents or 20.55 percent to 8.8 cents with 642,444 shares traded.

IDT AUSTRALIA

IDT says US Food and Drug Administration regulatory requirements for "a North American pharmaceutical client" will delay a previously expected improvement in revenue and profit. In February IDT said in its report for the six months to December 31, 2012 that "based on current forecasts and subject to the usual caveats the directors expect a much improved performance in the second half" (BD: Feb 26, 2013).

Today IDT said that "as a result of further FDA regulatory requirements there will be delays in the timing of its [client's] large development project" until the 2013-'14 financial year.

IDT provides product manufacturing and conducts research and development for the client.

The company said that as a result of this delay, the financial result for six months to June 30, 2013 would be similar to the results for the six months to December 31, 2012, which showed revenue was up three percent to \$5,090,000 with a net loss after tax up 25.1 percent to \$967,000.

IDT was unchanged at 24.5 cents.

PROGEN PHARMACEUTICALS

Progen expects to raise about \$5.19 million through an underwritten non-renounceable pro-rata one-for-one rights issue at 21 cents a share.

Progen said that the funds would be used for preclinical and clinical development of PG545, continued development of PI-88 and be used for capital works on the manufacturing facility of wholly-owned subsidiary Pharmasynth Pty Ltd to increase production capacity and broaden the scope of Pharmasynth services.

The company said that the rights issue was underwritten by Mercer Capital Pty Ltd Progen said the record date for the offer would be April 26, the opening date would be May 1 and the offer would close on May 15, 2013.

Progen was untraded at 20 cents.

SUDA (FORMERLY EASTLAND MEDICAL SYSTEMS)

Suda says that scale-up manufacturing of sub-lingual Artimist for paediatric malaria has been completed by Canadian contract manufacturer Therapex.

Suda said scale-up batches had been completed and manufactured product had passed quality assurance testing.

The company said that the scale-up was "an important step in the commercialization process".

Suda was unchanged at 3.1 cents with 1.3 million shares traded.

NEURODISCOVERY

Neurodiscovery says it has completed the acquisition of Enigma Therapeutics and intends to change its name to Oncosil Medical.

Neurodiscovery said it would seek shareholder approval for the name change.

Neurodiscovery fell 0.3 cents or 8.1 percent to 3.4 cents.

THE UNIVERSITY OF SYDNEY

The University of Sydney Medical School will host a student-organized Tedmed affiliated conference to help drive medical innovation on April 20, 2013.

Tedmed is a subsidiary of the Technology, Entertainment, Design (Ted) conferences and was described on its website as "a multi-disciplinary community of innovators and leaders who share a common determination to create a better future in health and medicine".

The Tedmed site said that once a year at the Kennedy Center in Washington, DC, the organization curated "an unusual and provocative three and half day program [featuring] brilliant short talks and stunning artistic performances that celebrate the power of unexpected connections to create important new possibilities".

The University of Sydney event will feature National Health and Medical Research Council chief executive officer Prof Warwick Anderson, the Brain and Mind Institute's Prof Ian Hickie, the Boden Institute's Prof Amanda Sainsbury-Salis and the Garvan Institute's Dr Paul Baldock.

For more information or to register to attend visit www.tedmedsydney.com.