



Biotech Daily

Friday March 22, 2013

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: PHYLOGICA UP 14%, PHARMAXIS DOWN 5.5%**
- * **BENITEC PREPARES FOR US PHASE I/II TT-034 HEPATITIS C TRIAL**
- * **NANOSONICS, GE SELL 21 TROPHONS TO SCRIPPS**
- * **ALCHEMIA APPOINTS NATHAN DRONA, DR SUSAN KELLEY DIRECTORS**
- * **ACUVAX EGM APPROVES BIOLIFE ACQUISITION, NAME CHANGE**
- * **AUSTRALIAN COMPOSITION-OF-MATTER PATENT FOR PHYLOGICA**
- * **VIRALYTICS CLAIMS REFLECTED GLORY FROM AMGEN PHASE III TRIAL**
- * **ABC-TV'S 'THE CHECKOUT' SLAMS TGA, COMPLIMENTARY MEDICINE**

MARKET REPORT

The Australian stock market was up 0.16 percent on Friday March 22, 2013 with the S&P ASX 200 up 7.9 points to 4,967.3 points.

Eight of the Biotech Daily Top 40 stocks were up, 14 fell, 14 traded unchanged and four were untraded. All three Big Caps fell.

Phylogica was the best, up 0.3 cents or 14.3 percent to 2.4 cents, with 353,000 shares traded.

Reva climbed 6.1 percent; Atcor, Tissue Therapies and Viralytics were up more than three percent; Neuren rose 2.9 percent; with Mesoblast and Bionomics up more than one percent.

Pharmaxis led the falls, down 2.5 cents or 5.5 percent to 43 cents with 1.2 million shares traded.

Living Cell and Prima fell four percent or more; Allied Health, Anteo, Genetic Technologies and Medical Developments were down three percent or more; Alchemia, Clinuvel and Prana shed two percent or more; Cochlear and Nanosonics were down more than one percent; with CSL, Heartware, Psivida, Resmed and Sirtex down by less than one percent.

BENITEC BIOPHARMA

Benitec says its phase I/II first-in-man trial for TT-034 for hepatitis C will be held at the Durham, North Carolina-based Duke Clinical Research Unit

Benitec said that the DNA-directed RNA-interference (ddRNAi) TT-034 compound was being developed as a potential one-shot-cure for hepatitis and the trial marked the transition to a clinical stage company.

Benitec chief executive officer Dr Peter French said that he expected that positive results from the trial would provide “a value inflection point for the company and also be a validation for our ddRNAi technology as an effective platform for therapeutics”.

The company said that the phase I/II clinical trial was an open-label dose escalation study to evaluate the safety and activity of single doses of TT-034 in patients with chronic hepatitis C virus genotype 1 infection who had failed previous treatments.

Benitec said that the trial was expected to involve 14 patients in five sequential dose cohorts, with additional cohorts added during the study to confirm the results.

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

Benitec said there was a pre-specified interim read on safety and activity within months of the trial beginning, with patient enrolment expected to begin by the end of 2013.

The company said that Duke’s principal investigator would be Dr Keyur Patel who had previous experience with oligonucleotide therapeutics in hepatitis C virus (HCV) and had more than 100 citations in peer-reviewed publications.

Benitec was unchanged at 1.2 cents with 2.5 million shares traded.

NANOSONICS

Nanosonics says that GE Healthcare has sold an initial order of 21 Trophon EPR ultrasound probe disinfection units to the San Diego-based Scripps Health network.

Nanosonics chief financial officer McGregor Grant told Biotech Daily that he expected the roll-out to Scripps to be “a significant multiple” of the initial order.

The company has previously said the units would retail for about \$10,000 each with Nanosonics receiving about half of the sale price.

Nanosonics said that Scripps was a private, non-profit, integrated health system treating 500,000 patients a year at five acute-care hospital campuses and 24 outpatient centers.

The company said Scripps had plans “to introduce significantly more of the devices, as it transitions from a manual to a fully-automated process for the high level disinfection of ultrasound probes”.

Scripps’ Gooding Imaging Center manager Eric Rosenberg said that Scripps was “focused on remaining a leader in making improvements in healthcare through the use of innovative technology”.

“We are in the process of converting most sonography high level disinfection of endo-vaginal probes from a manual ... cleaning process to an automated high level disinfection cleaning process,” Mr Rosenberg said. “We have selected the Trophon EPR device to achieve this goal.”

Mr Rosenberg said the Trophon system improved efficiency, created more standardization, reduced chances for human error and “reduced exposure to harsh chemicals previously used during the manual cleaning process”.

Nanosonics chief executive Dr Ron Weinberger said the Scripps purchase demonstrated growing awareness of Trophon EPR among healthcare facilities in a key US market.

Nanosonics fell half a cent or one percent to 47.5 cents.

ALCHEMIA

Alchemia says it has appointed Dr Susan Kelley and Nathan Drona as non-executive directors.

In 2010, Avexa shareholders voted overwhelmingly to remove the then chairman Mr Drona and recently appointed director Uri Ratner (BD: Jul 6, 8, 2010).

Today, Alchemia chairman Dr Mel Bridges said Dr Kelley and Mr Drona brought “substantial drug development, oncology, investment banking and biotechnology experience to the company”.

“These US appointments will substantially assist our endeavor to position Alchemia Limited and Audeo as global biopharma companies, with a solid presence in North America and Europe,” Dr Bridges said.

Alchemia said that Mr Drona had a 15 year career in investment banking, most recently as managing director of Challiss in New York and Sydney.

In 2010, Avexa shareholders removed Mr Drona and Mr Ratner from the board, with sources at the meeting telling Biotech Daily that “the board was pounded by small shareholders” (BD: Jul 6, 8, 2010).

In May, Avexa closed its lead program developing apricitabine for HIV, announced the resignation of chief executive officer Dr Julian Chick and received the call to remove Mr Drona, along with any board member appointed between May 6, 2010 and the date of the general meeting (BD: May 10, 20, 2010).

Also in May 2010, Orbis Investment Management, now Allan Gray Australia, ceased its substantial holding in Avexa losing \$5,968,500 on its investment, buying shares in 2008 and 2009 at an average of 15.6 cents a share and selling at an average of 3.1 cents a share (BD: May 21, 2010).

Mr Drona was appointed chairman of Avexa in 2008 when the company’s share price was 14.5 cents (BD: Oct 6, 2008).

Alchemia said that Dr Kelley was a director of Audeo Oncology and Arqule Inc since April 2011 and that from 2001 to 2008, Dr Kelley was employed by Bayer Healthcare Pharmaceuticals and Bayer-Schering Pharma in Germany and the US and from 2002 to 2008 was oncology vice president, global clinical development and therapeutic area head. Alchemia said that from 2008 to 2011, Dr Kelley was the chief medical officer of the Multiple Myeloma Research Foundation Consortium.

The company said that Dr Kelley was a Doctor of Medicine from Duke University School of Medicine and was a professor of medicine at Yale University School of Medicine.

In November last year, Alchemia chairman Dr Mel Bridges said he intended to retire from the company “in the approach to the end of the financial year” (BD: Nov 22, 2012).

According to an Alchemia presentation Allan Gray and Orbis owned 19.0 percent of the company and according to the 2012 Annual Report, Jagen Nominees, a company associated with Bori Liberman and Lawrence Gozlan, held 4.57 percent of the company, with Phillip Asset Management holding 3.42 percent.

Alchemia fell one cent or 2.8 percent to 35 cents.

ACUVAX

All resolutions to the Acuvax change of activities and name, backdoor listing extraordinary general meeting were passed overwhelmingly.

Acuvax shareholders approved the Biolife Science acquisition and name change to Biolife Science, the 200-to-one consolidation and raising \$5,000,000 through the placement of 25,000,000 shares at 20 cents each (BD: Dec 20, 2012; Feb 12, 18, 2013).

Acuvax was untraded at 0.1 cents.

PHYLOGICA

Phylogica says it has been granted an Australian patent covering its core composition of matter claims.

Phylogica said that the patent, entitled 'Isolating biological modulators from biodiverse gene fragment libraries', covered its Phylomer libraries as composition-of-matter, regardless of how the libraries were constructed or screened.

The company said that there was no restriction on the source of genomes represented in any Phylomer library, provided that the sequenced genomes were compact and the definition allowed for the libraries to be comprised of biodiverse genomes, not simply from bacteria and archaea, but also covering libraries from more complex eukaryotic genomes such as those of yeast, protozoa, algae and even vertebrates such as the Japanese puffer fish *Takifugu rubripes*.

Phylogica said that the patent complemented other composition-of-matter patents granted in major jurisdictions, including a European patent covering phage display Phylomer libraries.

Phylogica chief executive officer Dr Paul Watt said that new Australian and European patents confirmed his company's intellectual property position over the Phylomer peptide class.

"Our Phylomer libraries, which now encode more than 170 billion compounds, represent the most structurally diverse source of peptides available due to their unique composition," Dr Watt said.

"Our [intellectual property] estate blocks potential competitors and controls access to this rich resource of drug-like peptides by any current or future means, since we have protected the Phylomer libraries themselves, in addition to multiple methods of constructing and screening them," Dr Watt said.

"These newly granted patents also protect Phylogica's recent upgrades to the Phylomer platform, which have enhanced the overall complexity of the phage libraries and allow for the inclusion of selected bacterial and viral genes with known cell-penetrating and cell-targeting properties as a source of new delivery peptides," Dr Watt said.

Phylogica was up 0.3 cents or 14.3 percent to 2.4 cents.

VIRALYTICS

Viralytics says Amgen's phase III trial success with investigational product, Talimogene Laherparepvec (T-Vec) is generally good for oncolytic virotherapy

Viralytics is developing Coxsackievirus A21 as Cavatak for cancers including a phase II trial for late stage melanoma (BD: Mar 21, 2013).

Viralytics said that Amgen reported that its phase III study in over 400 late stage melanoma patients met the primary endpoint of superior durable response rate defined as the rate of complete or partial response lasting continuously for at least six months in T-Vec versus control treated patients.

The company said that T-Vec was an investigational product based on a genetically modified cancer-killing herpes virus injected directly into the tumor.

Viralytics chief executive officer Dr Malcolm McColl said the Amgen trial was "a milestone event for the field of oncolytic virotherapy with success in meeting the primary endpoint in a controlled phase III study".

"Amgen's achievement reflects well on our sector of targeted cancer biologics, encouraging further pivotal clinical evaluation of such novel oncolytic agents," Dr McColl said.

Viralytics was up one cent or 3.2 percent to 32.5 cents.

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION

The premier edition of The Checkout on ABC-TV last night investigated complimentary medicines and was highly critical of the Australian Therapeutic Goods Administration. The program described the system as “a joke” and the TGA in even more disparaging terms.

The Checkout is a co-production between the ABC and Jigsaw Dwarf, an amalgam of Giant Dwarf (The Chaser) and Cordell Jigsaw Zapruder (formerly Zapruder's Other Films). The Checkout's TGA item is at: <http://www.youtube.com/watch?v=nH8GwjLZ9IE>.