



# Biotech Daily

Thursday May 2, 2013

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH DOWN: PHYLOGICA UP 13%, MEDICAL DEVELOP DOWN 12%**
- \* **CYCLOPHARM'S TECHNEGAS 'COULD HELP DETECT, MANAGE COPD'**
- \* **PSIVIDA, ALIMERA NEW US PDUFA DATE FOR ILUVIEN FOR DME**
- \* **ST VINCENT'S INSTITUTE RESEARCH FORUM 'UNLEASHING INNOVATION'**
- \* **OBJ PREPARES FOR TRANSDERMAL INTERNET COSMETIC CRÈME TRIAL**
- \* **MASS MUTUAL REDUCES TO 8% IN NOVOGEN**
- \* **CRAIG HITCHINS REPLACES MEDIVAC DIRECTOR JOHN EVANS**

## MARKET REPORT

The Australian stock market fell 0.7 percent on Thursday May 2, 2013, with the S&P ASX 200 down 36.2 points to 5,130.0 points.

Ten of the Biotech Daily Top 40 stocks were up, 18 fell, seven traded unchanged and five were untraded. All three Big Caps fell.

Phylogica was the best for the second day in a row, up 0.2 cents or 13.3 percent to 1.7 cents, with 2.5 million shares traded.

Benitec climbed 7.7 percent; Neuren and Uscom were up five percent or more; Universal Biosensors was up 4.1 percent; Optiscan and Viralytics climbed more than three percent; Sirtex rose 2.5 percent; Anteo was up 1.9 percent; with Reva up one percent.

Medical Developments led the falls, down 18 cents or 12.4 percent to \$1.27 with 80,611 shares traded, followed by Cellmid down 11.1 percent to 2.4 cents with 2.7 million shares traded.

Prima fell 6.3 percent; Avita and Starpharma lost five percent or more; Phosphagenics fell 4.35 percent; Allied Health, Circadian, Patrys and Pharmaxis were down more than three percent; Alchemia, Bionomics, Cochlear, Genetic Technologies and Nanosonics shed more than two percent; with CSL, Impedimed and Mesoblast down more than one percent.

## CYCLOPHARM

Cyclopharm says its Technegas may be able to be used for the early diagnosis and management of chronic obstructive pulmonary disease (COPD).

Cyclopharm said that a mouse model study had shown that Technegas was effective in detecting early changes to the lungs, often caused by cigarette smoke, in advance of traditional computed tomography (CT) scans.

The company said that an article published in the North American Journal of Nuclear Medicine by researchers from Hamilton Ontario's McMaster University and the Firestone Institute for Respiratory Health at St. Joseph's Healthcare in Ontario "demonstrated that Technegas detected changes in lung ventilation and perfusion before structural changes in the lungs were detected by CT scans".

An abstract of the article, entitled 'Detection of Lung Dysfunction Using Ventilation and Perfusion SPECT in a Mouse Model of Chronic Cigarette Smoke Exposure' is available at: <http://www.ncbi.nlm.nih.gov/pubmed/23397007>.

Cyclopharm managing director James McBrayer said that Technegas was primarily used to diagnose pulmonary embolism, but clinicians had used the technology in several other indications.

"This research in relation to COPD underscores the validity of the work we have been doing in expanding our life-saving technology," Mr McBrayer said.

Cyclopharm said the study concluded "Lung ventilation and perfusion imaging [using Technegas] can detect early changes to the lung caused by cigarette smoke exposure and thus provides a non-invasive method of longitudinally studying lung dysfunction in preclinical models".

"In the future, these measures could be applied clinically to study and diagnose the early stages of chronic obstructive pulmonary disease," the study concluded.

Cyclopharm said it recently began a 500-patient pilot clinical trial targeting the use of Technegas in chronic obstructive pulmonary disease at five locations in China and was expected to conclude in 2014.

The company said that it expected initial results from the trial by the end of 2013, which would provide an indication of the effectiveness of Technegas in COPD diagnosis, and consequently the potential market size to Cyclopharm.

Study co-ordinator and senior researcher at Sydney's Woolcock Institute Dr Michael Guo said the Technegas pilot study was designed "to evaluate lung imaging in terms of morphological and functional changes in assessing COPD severity and developing a more effective algorithm to identify other diseases associated with COPD."

"This study could declare a revolutionary method in assessing COPD," Dr Guo said.

Cyclopharm quoted a 2008 Lancet study predicting that China would have 65 million deaths from COPD and 18 million deaths from lung cancer between 2003 and 2033, driven in a large part from smoking and biomass burning in the home.

"China is a very important market for Cyclopharm," Mr McBrayer said.

"In 2012, we have seen significant growth with Technegas sales and the upward trajectory is continuing into 2013," Mr McBrayer said.

Mr McBrayer said that in China, respiratory diseases including COPD were among the leading causes of death, with about half of Chinese men smoking and more than 70 percent of homes using wood and coal for heating and cooking.

Cyclopharm said that there was no cure for COPD, but there was strong evidence to show that early diagnosis, combined with disease management programs, could reduce its burden, improve quality of life, slow disease progression, reduce mortality and keep people out of hospital and Technegas could assist in its diagnosis and management.

Cyclopharm was unchanged at 18 cents.

## PSIVIDA

Psivida says the US Food and Drug Administration has provided a new Prescription Drug User Fee Act goal date of October 17, 2013 for Iluvien for diabetic macular oedema. Psivida said that the FDA acknowledged receipt of the new drug application for Iluvien and the resubmission was considered a complete, class 2 response to the FDA's 2011 complete response letter, refusing the original application (BD: Nov 14, 2011). Psivida said that licensee Alimera Sciences responded to the FDA's complete response letter and provided additional analyses as well as new information to support Iluvien as safe and effective in the treatment of patients with chronic diabetic macular oedema. The company said that using data from Alimera's two phase III clinical trials (the Fame study), the resubmission focused on the safety aspects of Iluvien and the subgroup of patients with chronic diabetic macular oedema (DME), the same subgroup for which Marketing approval for Iluvien has been granted in six countries in the European Union. Psivida said that at 36 months of treatment the difference in the proportion of 15 Early Treatment Diabetic Retinopathy Study eye chart letter responders between Iluvien and the control was more than twice that seen for the overall population. The company reported that Alimera believed that the resubmission package included important new information that demonstrated the safety and efficacy of Iluvien for patients suffering from chronic diabetic macular oedema and that a clearer position existed for Iluvien in the treatment of diabetic macular oedema patients. Psivida chief executive officer Dr Paul Ashton said that if the FDA approved Iluvien, "we would be entitled to an additional \$US25 million milestone payment from Alimera as well as 20 percent of net profits as defined on any sales in the US by Alimera". "We are entitled to the same net profit share on sales of Iluvien for DME by Alimera in the EU, where Alimera has already launched in the UK and reported plans to launch in Germany in 2013," Dr Ashton said. Psivida was untraded at \$2.03.

## ST VINCENT'S INSTITUTE

The St Vincent's Institute 14th annual Research Forum, entitled 'Unleashing Innovation' will be held on May 20, 2013. The St Vincent's Institute said that "innovation succinctly articulates the purpose of St Vincent's Institute and medical research in general: applying discoveries to create value". The Institute said the Australia had been "very good" at discovery and invention, but less adept at doing something useful and productive with that discovery. The Institute said that the key ingredients in innovation included a highly educated work force, very good technology and, above all, collaboration across disciplines. The Institute said that the Unleashing Innovation forum would be chaired by its patron Prof Gus Nossal and explore what can be done to make us a more innovative nation. The Forum will discuss innovation with CSL research and development director and chief scientist Dr Andrew Cuthbertson, science writer and broadcaster Leigh Dayton and the founder of Robogals, Marita Cheng. The Forum will be held at The Edge theatre, Federation Square, Cnr Swanston Street and Flinders Street, Melbourne on May 20, 2013 at 12pm (AEST). To register, email: [enquiries@svi.edu.au](mailto:enquiries@svi.edu.au) or telephone St Vincent's Institute reception on +613 9288 2480.

## OBJ

OBJ says it has manufactured and shipped the first clinical trial Eskin units to partner Coty Inc's skin care division Philosophy's US contract research organization.

OBJ said the trial units were developed in consultation with Coty's teams in the US and Europe and would be evaluated in an independent clinical efficacy study in the US to prove efficacy in humans for marketing claims and, subject to success in the clinical trial, as a pre-cursor to potential licencing, supply and global distribution.

The company said that Eskin incorporates its Dermaportation powered transdermal delivery technology that had been shown "to enhance the delivery of key anti-aging and skincare ingredients deeper and more effectively into the skin".

OBJ said that the trial was designed "to demonstrate consumer perceivable levels of performance improvement including more rapid reduction of fine lines and wrinkles in comparison with the commercial formulation applied by hand".

The company said that if the trial was successful it would be "a major step forward ... in the potential commercial development of its powered drug delivery technology and its web-enabled personalization capabilities that allow Eskin to optimize cosmetic delivery precisely to individual needs via the world wide web using portable devices".

OBJ was unchanged at 1.1 cents with 1.5 million shares traded.

## NOVOGEN

Oppenheimer Funds entity Massachusetts Mutual says it has reduced its substantial holding in Novogen from 11,038,532 shares (9.40%) to 10,222,889 shares (7.75%).

The substantial shareholder notice, filed by the Sydney office of law firm, DLA Piper, for the Massachusetts-based MM Asset Management said that the company sold 815,643 shares for \$77,943 or an average price of 9.55 cents a share.

In February MM Asset Management sold 514,180 shares for \$57,412 or an average price of 11.2 cents a share. (BD: Feb 15, 2013)

Novogen fell one cent or 5.6 percent to 17 cents with 1.2 million shares traded.

## MEDIVAC

Medivac says that Craig Hitchins has been appointed as a director replacing John Evans, effective on April 29, 2013.

Medivac said that Mr Hitchins was a fund manager with experience in the banking and finance industry and held senior management roles for more than 25 years.

The company said that Mr Hitchins was previously employed by Challenger Commercial Lending for 20 years, where he was the head of commercial lending and prior to that he held senior management roles with major banks.

Medivac was untraded at 0.5 cents.