



Biotech Daily

Wednesday October 3, 2012

Daily news on ASX-listed biotechnology companies

VALE PROF NANCY MILLIS 1922 – 2012

- * ASX EVEN, BIOTECH DOWN: ALLIED UP 9%, PHYLOGICA DOWN 7%**
- * RESEARCH REVIEW CALLS FOR UP TO \$3.6b MORE PER YEAR**
- * AUSBIOTECH TRIBUTE TO PROF NANCY MILLIS, BIOTECH'S 1st LADY**
- * GI DYNAMICS ENDOBARRIER NON-OBESSE INSULINE SENSITIVITY BENEFIT**
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- * ISONEA APPLIES FOR US SONOSENTRY OTC SALES**
- * CONSEGNA BREATHEASSIST MEETS TRIPLE A SALES DUE DILIGENCE**
- * BAILLIE GIFFORD TAKES 9.6% OF COCHLEAR**
- * THEE WOON GOH TAKES 12% OF NUSEP**

MARKET REPORT

The Australian stock market was up 0.13 percent on Wednesday October 3, 2012 with the S&P ASX 200 up 5.6 points to 4,438.6 points.

Twelve of the Biotech Daily Top 40 stocks were up, 16 fell, eight traded unchanged and four were untraded.

Allied Health was the best, up 0.2 cents or 9.1 percent to 2.4 cents with 54,166 shares traded. Bioniche climbed 7.5 percent; Anteo and Circadian were up more than five percent; Living Cell and Reva rose two percent or more; with Biota, Clinuvel, Heartware, Mesoblast, Nanosonics and Resmed up more than one percent

Phylogica led the falls, down 0.2 cents or 7.1 percent to 2.6 cents with 1.2 million shares traded. Cellmid, Neuren and Sunshine Heart lost more than six percent; Alchemia, Antisense, Impedimed, Patrys and Universal Biosensors fell five percent or more; Bionomics and Genetic Technologies were down more than four percent; Psivida lost 3.4 percent; Pharmaxis shed 2.1 percent; with CSL down 1.7 percent.

STRATEGIC REVIEW OF HEALTH AND MEDICAL RESEARCH IN AUSTRALIA

The Strategic Review of Health and Medical Research says up to \$3.6 billion more per year “should be invested in research [for] a better health system and other initiatives”. In the summary of the consultation paper published today the Review panel chair Simon McKeon said the panel spent months listening and absorbing information and received more than 340 formal contributions.

Mr McKeon said the panel began public meetings in mid-April which were held in every capital city, along with a series of private stakeholder consultations which included 75 meetings, covering over 175 different stakeholder groups and more than 200 individuals. Mr McKeon said the submissions showed “a considerable breadth and depth of issues, though clearly some key themes—such as workforce constraints and lack of indirect research cost support—were reiterated across the nation”.

“An overarching message that emerged from the plethora of evidence was the lack of a sufficiently strong connection between health and medical research and the delivery of healthcare services,” Mr McKeon said. “Thus, the panel's overarching vision for the future of health and medical research is one where research is fully embedded in all aspects of healthcare to deliver ‘Better Health Through Research’.”

In its executive summary, the Review said that health and medical research was the research and development arm of Australia’s \$130 billion health sector, “so investment in research is vital to support innovation, performance improvement and curtail escalating healthcare costs”.

“The vision is for a high quality and efficient health system, where a defined proportion of the health budget is invested in research in the health system and where all research activity is well managed to deliver health impact. Initially, the focus should be on spending current investment more effectively,” the Review said.

The Review said that within the next 10 years, an additional \$2 billion to \$3 billion a year should be invested in research as well as an additional \$400 million to \$600 million a year for other initiatives.

The Consultation Paper and recommendations are at www.mckeonreview.org.au with four weeks allowed for responses until October 31, 2012.

The Paper detailed seven major themes: embedding research within the health system; set and support research priorities; maintain research excellence; enhance non-commercial pathways to impacts; enhance commercial pathways to impacts; attract philanthropy through leveraging donations; and invest for the future.

The Consultation Paper said a robust implementation process should be implemented with a medium term follow-up review by the National Health and Medical Research Council and with oversight by an independent panel.

The Discoveries Need Dollars campaign welcomed the recommendations, with Walter and Eliza Hall Institute director Prof Doug Hilton saying the review panel had produced “an astute vision for how health and medical research should be conducted in Australia”.

“They have been realistic and fiscally prudent in their recommendations, ensuring they can be adopted without significant additional expenditure,” Prof Hilton said. “I urge the government and opposition to commit to fully adopting the review’s recommendations.”

Melbourne Health chief executive officer Dr Gareth Goodier and the University of Melbourne research deputy vice-chancellor ; Prof James McCluskey joined Prof Hilton in urging the Federal Government to adopt the recommendations of the independent review.

“If adopted by the government, these recommendations will allow Australia to maintain a vibrant research community, encourage the top students to direct their talents to health and medical research, and stem the loss of valuable and talented scientists from the Australian research sector,” Professor McCluskey said.

EMERITUS PROFESSOR NANCY MILLIS, AUSBIOTECH

Ausbiotech says that distinguished and highly-respected 'legend' of Australian biotechnology, Emeritus Professor Nancy Millis died last weekend.

Ausbiotech said that Prof Millis was an active member of the industry organization and an honorary life member.

Ausbiotech chief executive officer Dr Anna Lavelle said that Prof Millis "made a vast contribution to biotechnology as one of the pioneers of fermentation technology study in Australia [and] created the first applied microbiology course taught in an Australian university" and the annual Ausbiotech conference Millis Oration was named in honor of her contribution to the industry..

Ausbiotech said that Prof Millis had an illustrious career, which began with the pioneering study of biotechnology in Australia and culminated in her appointment as the chancellor of La Trobe University from 1992, a position she held until her retirement in 2006.

The organization said that Prof Millis's main areas of interest were the general field of biotechnology, fermentation, wastewater and environmental biotechnology.

Melbourne-born Prof Millis was originally refused entry into a University of Melbourne Bachelor of Science degree, but gained entry to agricultural science.

In 1945, Prof Millis graduated with a Bachelor of Agricultural Science and went on to complete a Master's degree studying the soil organism, *Pseudomonas* in 1946.

Ausbiotech said that Prof Millis worked in Papua New Guinea with the Department of External Affairs teaching women agricultural methods, but her posting was cut short by serious illness that almost claimed her life and she was airlifted to hospital in Brisbane.

After recovering, she applied for a Boots Research Scholarship at the University of Bristol, where she spent three years working on the fermentation of cider and micro-organisms.

Ausbiotech said that when Prof Millis completed her Ph D at the University of Bristol in 1951, she returned to Australia and hoped to work for Carlton United Brewery, but they did not employ women in their laboratories and she joined the University of Melbourne's Department of Microbiology in 1952.

Ausbiotech said that Prof Millis worked as a demonstrator and then as a lecturer, setting up the Applied Microbiology course at the university until 1982.

In 1954 Millis was awarded a Fulbright Travel Grant, went to Hopkins Marine Station at Stanford and then to the Institute of Applied Microbiology at the University of Tokyo.

The industry organization said that in 1982, Nancy Millis was appointed as a professor of Microbiology, making her the fourth woman to be appointed as a professor at the University of Melbourne, a position that she held until 1987.

In 1988 Prof Millis was appointed Emeritus Professor of the University of Melbourne and in 1993, the university awarded her an honorary Doctorate of Science.

University of Melbourne Bio21 Cluster chief executive Dr Jan Tennent said Prof Millis was the "undisputed first lady of biotechnology and an inspiration to women in science".

Prof Millis was awarded a Member of the Order of the British Empire in 1976 for work in biological sciences and education and a Companion of the Order of Australia in 1990.

She was a Fellow of the Australian Academy of Technological Sciences and Engineering and an Honorary Life Member of the Australian Society for Microbiology.

Prof Millis was a board member of the Fairfield Infectious Diseases Hospital, the Australian Water Advisory Resources Committee, the Cooperative Research Centre for Freshwater Ecology, the Council of the Australian Academy of Technological Sciences, the National Commission for UNESCO and many other professional organizations.

Ausbiotech said that Prof Millis would be missed by the Australian biotechnology community and Biotech Daily applauds the industry organization's tribute.

GI DYNAMICS

GI Dynamics says further data from a study of its Endobarrier in overweight but non-obese patients shows improved insulin sensitivity.

In June, GI Dynamics released the first data from its 'Metabolic Improvement in Type 2 Diabetes in Subjects without Severe Obesity with the Endoscopic Duodenal-Jejunal Bypass Liner' trial (BD: Jun 25, 2012).

Today the company said that data presented by Imperial College London's Dr Dimitri Pournaras at the European Association for the Study of Diabetes meeting in Berlin Germany, demonstrated that Endobarrier therapy led to "improved glycaemic control in overweight and obese patients with type 2 diabetes due to improved insulin sensitivity observed early in the treatment period and sustained over one year".

The company said the findings provided further evidence for Endobarrier therapy for people with type 2 diabetes who were overweight, but not necessarily obese.

GI Dynamics said that the study's lead investigator Dr Ricardo Cohen of Hospital Oswaldo Cruz's in Sao Paulo, Brazil said the results "further demonstrate the effects and improvements Endobarrier therapy offers to patients with type 2 diabetes in gaining and maintaining glycemic control [and] Endobarrier therapy improves HbA1c early in the treatment period."

"Our research also reinforced the effects of Endobarrier therapy on insulin sensitivity and glucose metabolism, similar to that of gastric bypass, but without surgery or permanent alterations to the anatomy," Dr Cohen said.

GI Dynamics said the presentation was entitled 'Glycaemic control after endoscopically placed duodenal-jejunal bypass liner in patients with type 2 diabetes and body mass index between 23 and 36 kg/m²' and reviewed 16 patients with type 2 diabetes and a body mass index less than 35kg/m² with an average of 30.8 kg/m², implanted with the Endobarrier for one year to evaluate its effects on insulin sensitivity and glucose control.

GI Dynamics said that there was a significant improvement in insulin sensitivity from baseline ($p < 0.001$) and a significant reduction in HbA1c at one year from 8.6 percent at baseline to 7.5 percent ($p < 0.001$).

GI Dynamics was unchanged at 70 cents.

BENITEC BIOPHARMA

Benitec says chief scientist Dr Michael Graham has told a meeting that silencing the protein kinase C gamma gene produces effective pain relief in an animal model.

Benitec said that Dr Graham presented an update entitled 'Gene Therapy to Control Intractable Pain in Cancer Patients: A New Paradigm' at the Pain Therapeutics Summit in San Jose, California.

The company said that the research so far showed that the gene target, protein kinase C gamma (PRKCG), had been "well-validated as a key pain associated mediator [and] proof of concept has been obtained that silencing this gene in vivo produces effective pain relief in an animal model".

The company said that experiments were underway with scientists at Tetrad and at Stanford University to validate new constructs that target regions on PRKCG which are conserved between human and other species.

Benitec said the validation was essential for the subsequent toxicology and bio-distribution studies required by regulatory authorities prior to gaining approval for a clinical trial, which was targeted for 2013.

Benitec was unchanged at 1.5 cents.

NOVOGEN, MEI PHARMA

Novogen says the European Patent Office has issued patent 63.5 percent subsidiary MEI Pharma (formerly Marshall Edwards) a patent covering the composition of lead mitochondrial inhibitor candidate ME-344 and its use in treating cancer.

Novogen said the patent was expected to provide protection until September 2025.

MEI Pharma chief executive officer Dr Daniel Gold said the "key European patent further reinforces the intellectual property protection surrounding our portfolio of oncology drug candidates".

"While we continue to execute our phase I clinical trial for ME-344 and prepare for our upcoming phase II trials, we believe a strong patent estate will help to provide a clear development path forward and enhance our partnering efforts in the US and abroad," Dr Gold said.

MEI said its intellectual property portfolio included 18 issued US patents and more than 150 issued non-US patents.

Novogen was untraded at 7.2 cents.

NUSEP

Nusep says it has installed its first preparative isolation by membrane electrophoresis (Prime) unit in its Singapore therapeutic plasma products manufacturing facility.

Nusep said the installation was "a critical milestone" and would allow Prime Biologics to test run the manufacture of therapeutic plasma proteins paving the way for the delivery of the 250 litre therapeutic production unit in the next six months.

The company said that the Prime unit installed in Singapore was a 10L current good manufacturing practice compliant pilot scale unit and was capable of processing 10L batches of plasma and was a single unit of the disposable cartridge system to be installed. Nusep said that Prime would be manufacturing therapeutic plasma products in 250L batches and the 250L therapeutic production unit would consist of 25 single disposable cartridges operated as a single unit and the Singapore facility would process up to 150,000L of therapeutic plasma products in a full year.

The company said that Prime expected Singapore approval within 12 months.

Nusep said that Prime would begin processing currently unprocessable plasma (CUP) material for countries such as India once the clinical trial product had been manufactured.

Nusep was up 0.8 cents or 14.0 percent to 6.5 cents

ISONEA

Isona says it has applied to market the Sonosentry a re-branded non-prescription over the counter version of its Personal Wheezometer in the US.

Isona said it had submitted a 510(k) application for an equivalent device to the US Food and Drug Administration and that like the Wheezometer, the Sonosentry measured wheeze, a principal symptom of asthma.

Isona said the device used its acoustic respiratory monitoring (ARM) technology to calculate a Wheezerate the percentage of breathing time spent wheezing.

Isona chief executive officer Michael Thomas said that having the Sonosentry available over the counter "will make our unique ARM technology more broadly accessible".

"The Sonosentry provides an objective measurement of wheezing and can help asthmatics to monitor this symptom more accurately and easily," Mr Thomas said.

Isona said the typical FDA review period was 90 days.

Isona was up half a cent or 9.1 percent to six cents.

CONSEGNA GROUP

Consegna says Triple A Holdings is satisfied with the due diligence compendium for a global licence for the marketing and distribution of Breatheassist products.

Consegna said the parties were working towards a definitive agreement by October 31, 2012 which would call for payments of \$5 million for the licence and first year royalty with further minimum payments to Consegna of \$3 million in the second year, \$5 million in the third year, \$7 million in the fourth year and \$10 million in the fifth year or 25 percent of gross profit each year, whichever was greater.

Triple A chairman Stan Thomas said he was "really excited that we have found a way to work together to exploit the full potential of the Breatheassist product range and I remain cautiously optimistic that given the depth of the due diligence that is now behind us and our developing relationship, that the definitive agreement should be achievable by the end of the month".

Consegna was unchanged at 1.3 cents with 1.7 million shares traded.

COCHLEAR

Baillie Gifford & Co and associates have increased their substantial holding in Cochlear from 4,775,816 shares (8.39%) to 5,453,331 shares (9.57%).

The Edinburgh-based Baillie Gifford became substantial in Cochlear in August and has continued acquiring shares (BD: Aug 19, Oct 25, 2011; Feb 3, 2012).

Cochlear was up 59 cents or 0.9 percent to \$69.25 with 191,254 shares traded.

NUSEP

The Singapore-based Thee Woon Goh has become a substantial shareholder in Nusep with the acquisition of 13,182,691 shares or 11.86 percent.

The initial substantial shareholder notice said that Mr Goh acquired 13,182,691 shares for \$1,384,177 or 10.5 cents a share (see BD: Sep 27, 2012).