

Biotech Daily

Wednesday May 2, 2012

Daily news on ASX-listed biotechnology companies

- * ASX UP, BIOTECH DOWN: AVITA UP 10%, CELLMID DOWN 11%
- * VICTORIA BUDGETS \$35m FOR INNOVATION \$26m FOR SYNCHROTRON
- * BUDGET COMMENT: BIOTECH DAILY, AUSBIOTECH, BIO-MELBOURNE
- * HUMAN IMPLICATIONS FROM BIONICHE DOG CANCER DRUGS
- * HATCHTECH RAISES \$8m, APPOINTS DR ROSS MACDONALD CEO
- * OSPREY OPENS UP 5%
- * GI DYNAMICS TRIAL DATA PUBLISHED IN JOURNAL ARTICLE
- * METAL GROUP INCREASES TO 18% OF ALLIED HEALTH
- * ITL SELLS 'TROUBLED MALAYSIAN DISTRIBUTOR' FOR \$1.1m
- * ALLAN GRAY (ORBIS) REDUCES TO 8.5% OF ACRUX
- * IMUGENE BUYS CONSEGNA'S LINGUET
- * TISSUE THERAPIES PLEADS SCHULTZ TO ASX 22% QUERY
- * NANOSONICS REQUESTS CAPITAL RAISING TRADING HALT

MARKET REPORT

The Australian stock market was up 0.14 percent on Wednesday May 2, 2012 with the S&P ASX 200 up 6.4 points to 4,435.9 points. Nine of the Biotech Daily Top 40 stocks were up, 15 fell, 11 traded unchanged and five were untraded. All Big Caps were up.

Avita was the best, up two cents or 10 percent to 22 cents with 235,099 shares traded. Tissue Therapies climbed 6.1 percent; Allied Health was up 3.7 percent; Heartware and Mesoblast rose more than two percent; with Bionomics, Cochlear, CSL, Resmed and Reva up more than one percent.

Cellmid fell 0.2 cents or 11.1 percent to 1.6 cents with 12.7 million shares traded. Patrys and Prana lost more than nine percent; Bioniche was down six percent; Living Cell fell 4.6 percent; Anteo, Circadian, Neuren, Psivida and Sunshine Heart lost three percent or more; with Phosphagenics, Phylogica and Viralytics down two percent or more.

VICTORIA GOVERNMENT

The 2012-'13 Victoria Budget has allocated more than \$35 million for innovation, including \$26 million over four years for the Australian Synchrotron in Clayton.

The Minister for Innovation, Services and Small Business Louise Asher confirmed that the State Government would double the number of Victoria Prize and Victoria Fellowship awards on offer (BD: Nov 15, 2011).

On a Victoria Government media release Ms Asher said that there would be an increase in a range of other innovation scholarship and business-boosting initiatives

"The 2012-'13 Budget is about driving economic activity, productivity and jobs and delivers on the Coalition Government's commitment to promote and support innovation in Victoria," Ms Asher said.

"A \$5 million voucher program will promote the uptake of new skills and support businesses to exploit Victoria's world-class science and research capabilities," Ms Asher said.

"The 2012-'13 Budget also provides \$150,000 to assist innovative firms to showcase new products and processes in metropolitan and regional Victoria," Ms Asher said.

"This Budget sets out a clear plan to meet our challenges and position Victoria to take full advantage of future opportunities," Ms Asher said.

The media release said that \$474,000 had been committed to the Victoria Prize and the Victoria Fellowships to double the number of awards and promote excellence in the science and research community.

"The Victoria Prize honors the lifelong commitment and achievements of Victoria's finest researchers in science, technology and engineering and the Victoria Fellowships are awarded to early-career professionals so they can undertake international study," Ms Asher said.

"Increasing the number of these awards demonstrates the Coalition Government's commitment to furthering Victoria's status as the science and research capital of Australia," Ms Asher said.

"I am also pleased to announce that the number of Innovation Fellowships offered annually by the Victorian Endowment for Science, Knowledge and Innovation (Veski) will be increased with a new \$1.5 million commitment.

"An additional allocation of \$500,000 will enable Veski to work in partnership with Victorian schools, teachers and students to increase participation in the sciences and to improve the knowledge and expertise of science teachers," Ms Asher said.

Ms Asher said the Government had pledged \$1.8 million for the Victorian Research Scholarships to encourage Victorian researchers to take up science research posts overseas.

"We are also providing \$26 million towards a joint agreement with the Commonwealth Government to secure the operation of the Australian Synchrotron over the next four years," Ms Asher said.

"The Australian Synchrotron is an important part of Victoria's innovation infrastructure and this funding will ensure Victorian researchers and industry partners continue to have access to leading-edge scientific infrastructure to carry out research."

Biotech Daily asked Ms Asher's media officer whether any programs or staff had been cut in the Department of Business and Innovation, but at the time of publication there had been no reply.

BUDGET COMMENT:

Biotech Daily

The continued commitment of successive Victoria Governments to innovation and in particular life sciences is perhaps more important than the fact that we appear to have been spared any cuts, and may have received a small increase in expenditure.

That the Baillieu Government understands the importance of the investment in innovation by the previous Labor Governments puts this State Government ahead of its peers. The bipartisan approach to sunrise industries is akin to the Hamer-Cain support for the Arts in the 1970s and 1980s, resulting in the boom in Melbourne's entertainment choices.

Of course, the preference would be to see a \$1 billion fund for pivotal trials, but given the popular confusion of long-term investment for short-term spending, this is unlikely.

The State Government has recognized the Synchrotron's value and defied those calling for it to be closed. The Synchrotron is a great piece of kit that needs more customers.

The strengthening of the smaller grants is also welcome. That said, the Department of Business and Innovation appears to be very stretched and we hope that there is no further cost-cutting, hidden in the fine print.

David Langsam Editor

Ausbiotech

Ausbiotech chief executive officer Dr Anna Lavelle says that "for biotechnology, this is a status quo budget".

"However with the newly established Victorian Biotechnology Advisory Group (VBAC) now fully operational, I look forward to support in the next budget round for the Group's strategies to grow the Victorian bio-economy," Dr Lavelle said.

"VBAC's work reflects the Government's stated intention to take a 'coordinated approach to fostering innovation and promoting growth in Victoria's biotechnology industry,' and Ausbiotech will welcome support to improve the operating environment after the Ausbiotech Industry Position Survey 2012 showed that the economic and public policy environment for Australia remains a concern for the growth of biotechnology companies, with 38 percent saying it was working against their growth," Dr Lavelle said.

Bio-Melbourne Network

Bio-Melbourne Network chief executive officer Michelle Gallaher says that biotechnology's exemption in the State Budget "is certainly a relief, but to achieve economic growth and generate jobs, a holding pattern in innovation just won't cut it".

"A budget surplus is not necessarily an advantage for innovation industries in Victoria where confident investment by government is essential," Ms Gallaher said. "Slashing expenditure is not an economic growth strategy and a further reduction of 600 public servants is a concern," Ms Gallaher said.

"The collateral damage in this announcement may have a serious impact on innovation industries in Victoria. The implementation of innovation strategy requires financial as well as experienced and committed human resources," Ms Gallaher said.

BIONICHE LIFE SCIENCES

Bioniche says it is commercializing two canine cancer products, one related to its human cancer treatment, expected to be launched in North America in July 2012.

Bioniche said that Immunocidin was based on its mycobacterial cell wall technology from which Urocidin for human bladder cancer was derived.

The company said that Immunocidin was pending regulatory approval in Canada and the US as an immunotherapy for the intra-tumoral treatment of mixed mammary tumor and mammary adenocarcinoma in dogs.

Bioniche chairman and chief executive officer Graeme McRae said that the global incidence of canine cancer was about 4.2 million new cases a year.

"It is the leading disease-related cause of death in dogs, with approximately one in four dying of cancer," Mr McRae said.

The company said that mammary tumors were the second most common group of neoplasms in dogs, following skin tumors and were one of the most common tumors in female dogs, comprising about 50 percent of all cancer types.

Bioniche said canine cancer can involve surgery, radiation therapy or chemotherapy, but radiation therapy was difficult to access and chemotherapy was highly toxic, requiring handling by specially trained personnel.

The company said that radiotherapy and chemotherapy had similar side effects in animals as in humans such as anorexia, nausea, hair loss, anemia and major infections and cost from \$3,000 to more than \$15,000.

"The company believes that its canine cancer products will be more accessible than chemotherapy given that no special handling is required and the pricing will be cost effective," Mr McRae said.

Bioniche said the second canine cancer therapy would be investigated for its ability to restore white blood cells following chemotherapy.

Bioniche said that during the development of Urocidin for human bladder cancer, the mycobacterial cell wall technology was tested in a number of human cancer cell lines, including bladder, ovarian, colon, gastric and breast, as well as in canine cancer cell lines, including osteosarcoma and mammary, where it was shown to have direct anti-cancer activity with apoptosis (programmed cell death) in cancer cells.

The company said that the technology had been demonstrated to be synergistic with chemotherapeutic agents and a large amount of toxicity work had been completed to ascertain the product's safety for human use.

Bioniche said that one of the safety studies involved a number of dogs in an intravenous safety study and after administration of large doses of the product to these dogs, there were few side effects.

The company said that this work led to further analysis of an intra-venous therapy for canine cancer based on the same technology.

Bioniche said that chemotherapy commonly causes cytopenia, a deficiency in the number of cellular elements in the blood, including white blood cells as well as erythrocytes and platelets.

The company said that clinical studies showed that a single dose of the second product following chemotherapy treatment in healthy dogs "restores the number of white blood cells in the dog to normal levels within 24 to 48 hours with few side effects".

Bioniche said it was undertaking dose confirmation studies prior to conducting final licencing studies.

The company said it expected the work would be completed over the next six months, followed by regulatory applications to North America, Australia and Europe. Bioniche fell three cents or six percent to 47 cents.

HATCHTECH

Hatchtech says it has raised \$7.8 million and appointed Dr Ross Macdonald as its chief executive officer ahead of pivotal phase III trials of its Deovo head lice treatment. In 2010 Hatchtech raised \$6.7 million for a phase IIb trial and last year said that 140 patient trial showed statistical significance in killing both lice and their eggs (BD: Oct 26, 2010; Dec 16, 2011).

Today, Dr Macdonald told Biotech Daily that the company would need about \$23 million for the 120-patient phase III pivotal trial and the company had sufficient funds for at least a further 12 months.

In a media release Hatchtech said that Dr Macdonald had 24 years experience in the pharmaceuticals industry and was directly involved in the development and global commercialization of several successful head lice treatment products.

Dr Macdonald said he was appointed a director of the company in January 2010. He was formerly the chief executive officer of Living Cell Technologies and had recently acted as a consultant to Consegna

Hatchtech said that Dr Macdonald was previously the head of business development for Sinclair Pharmaceuticals and prior to the corporate development vice-president for Stiefel Laboratories.

Hatchtech is a private company.

OSPREY

Osprey began trading on the ASX today under the code OSP, opening up two cents or five percent to 42 cents.

The company raised \$20 million in its initial public offer to develop and commercialize its Cincor contrast-induced nephropathy removal system (BD: Mar 1, 8, 2012).

Osprey closed at 42 cents with 384,890 shares traded.

GI DYNAMICS

GI Dynamics says that data on the efficacy of its Endobarrier for obesity and type 2 diabetes has been published in the journal, Annals of Surgery.

The company said the data, previously published in its prospectus, was from its first study evaluating the efficacy and safety of 12 months of Endobarrier therapy in an obese and mostly non-diabetic patient population.

GI Dynamics said the study found that the Endobarrier produced an average of 20 percent total body weight loss and significant improvements in cardiovascular risk factors and metabolic functions.

The article is entitled 'Weight Loss and Metabolic Improvement in Morbidly Obese Subjects Implanted for 1 Year With an Endoscopic Duodenal-Jejunal Bypass Liner' and an abstract is at: http://www.ncbi.nlm.nih.gov/pubmed/22534421.

GI Dynamics was up five cents or five percent to \$1.05.

ALLIED HEALTHCARE GROUP

The Metal Group has increased its substantial holding in Allied Health from 106,719,141 shares (14.69%) to 140,996,274 shares (17.84%).

The Metal Group is associated with Western Australian miner Andrew Forrest and said it acquired the 34,277,133 shares at 2.8 cents each.

Allied Health was up 0.1 cents or 3.7 percent to 2.8 cents with 2.6 million shares traded.

<u>ITL</u>

ITL says it has sold its 'troubled Malaysian distributor' ITL SEA Sdn Bhd and its wholly owned subsidiaries, for \$1.1 million, effective from January 1, 2012 (BD: Apr 5, 2012). The company said the Kuala Lumpur-based subsidiary, marketed and distributed medical equipment and consumables to Malaysian hospitals and medical centres.

ITL said the accounting treatment would showing a once-off loss of about \$900,000 and the ITL Group was debt free.

ITL fell half a cent or 2.9 percent to 17 cents.

ACRUX

Allan Gray Australia, formerly Orbis Investment Management, has reduced its substantial holding in Acrux from 16,201,958 shares (9.73%) to 14,129,941 shares (8.49%) Allan Gray said that it sold 2,072,017 shares between April 26 and 30, 2012 for \$8,315,829 or an average price of \$4.01.

Last week Allan Gray said it reduced its holding in Acrux by 1,710,934 shares or one percent, with the single largest sale 1,625,570 shares for \$6,470,370 or \$3.98 a share (BD: Apr 29, 2012).

Acrux was unchanged at \$4.05 with 1.2 million shares traded.

CONSEGNA, IMUGENE

Imugene will acquire Consegna subsidiary Lingual Consegna, the two companies said in media releases.

The media releases said that Lingual Consegna owned the rights to a family of patents and applications protecting the drug delivery platform technology Linguet which had application in human and animal pharmaceutical and food additive industries. Imugene said it would issue 100 million shares to Consegna for the acquisition. Consegna acquired all the rights to Linguet by issuing 25,000,000 shares to the original owner Ozpharma (BD: Apr 27, 2012).

Last year, Novartis terminated its licence agreement for development and commercialization of Imugene's vaccines for pigs and poultry (BD: Sep 2, 2011). Imugene said it would raise \$1 million through the issue of 100 million shares at one cent each to clients of Forrest Capital and CPS Securities to assist funding the expanded Imugene drug delivery technologies, along with 50 million unlisted adviser options issued, at 0.01 cents each and exercisable at two cents by December 31, 2015. Imugene managing director Dr Warwick Lamb said his company looked forward to working with the Consegna team to complete the development of the asset. Consegna managing director Fabio Pannuti said his company was "delighted to have taken this next step forward in identifying a suitable partnering team and vehicle in which to place our developing technology".

"This provides the funding to apply a dedicated scientific team to turn Linguet into a near term cash flow generating asset by focusing on product based commercial solutions," Mr Panutti said.

The companies said the Linguet tablet was placed under the tongue or the buccal cavity in the mouth and allowed to dissolve releasing the active drug, which was absorbed into the blood stream via the mucosa of the mouth, by-passing the gastrointestinal tract and able to reach its target more rapidly and with significantly lower side effects.

Consegna fell 0.2 cents or 6.1 percent to 3.1 cents.

Imagene was up 0.7 cents or 77.8 percent to 1.6 cents with 1.8 million shares traded.

TISSUE THERAPIES

Tissue Therapies has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities. The ASX said the company's share price rose from 45 cents on April 26, 2012 to 55 cents on May 2, 2012, a 22.2 percent increase and noted an increase in trading volume. Tissue Therapies climbed three cents or 6.1 percent to 52 cents with 1.3 million shares traded.

NANOSONICS

Nanosonics has requested a trading halt "pending an announcement to the market concerning a material fundraising".

Trading will resume on May 4, 2012 or on an earlier announcement. Nanosonics last traded at 50 cents.