Biotech Daily

Wednesday May 9, 2012

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ELLEX UP 6%, PHOSPHAGENICS DOWN 10%**

*** FEDERAL BUDGET: NHMRC, ARC FUNDING UP $85m, PBS DOWN $164m**

*** COMMENT: BIOTECH DAILY, AUSBIOTECH, GBS, BIO-MELBOURNE**

*** BIODIEM, VIVALIS COLLABORATE ON VIRUS VECTOR**

*** GENETIC TECHNOLOGIES SETTLES GENESEEK PATENT SUIT**

*** HEARTWARE COMPLETES HEART PUMP DESTINATION ENROLMENT**

*** CATHRX TO RAISE $12m, DELIST, SELL BUSINESS**

*** BLUECHIIP HIRES PLEXUS FOR MATCHBOX TAG READERS**

MARKET REPORT

The Australian stock market fell 0.91 percent on Wednesday May 9, 2012 with the S&P ASX 200 down 39.2 points to 4,275.1 points.

Seven of the Biotech Daily Top 40 stocks were up, 21 fell, seven traded unchanged and five were untraded.

Ellex was the best, up one cent or 5.9 percent to 18 cents with 55,000 shares traded.

Prana climbed 3.6 percent; Anteo, Avita and Genetic Technologies rose more than two percent; Biota was up 1.8 percent; with Cochlear, Heartware and Resmed up by less than one percent.

Phosphagenics led the falls, down two cents or 10 percent to 18 cents with 7.8 million shares traded.

Viralytics lost 9.1 percent; Cellmid, Phylogica and Prima fell five percent or more; Neuren and Pharmaxis were down four percent or more; Allied Health, Nanosonics and Patrys were down more than three percent; Alchemia, Genera, Sirtex and Tissue Therapies shed more than two percent; Bionomics, Living Cell, Reva and Starpharma were down more than one percent; with Acrux, Clinuvel, CSL and Mesoblast down by less than one percent.

FEDERAL BUDGET

Last night’s Federal Budget appears to be generally neutral or slightly positive to innovation and biotechnology.

Treasurer Wayne Swan’s Budget included increases to the National Health and Medical Research Council and Australian Research Council budgets of $14.4 million and $70.3 million, respectively.

The Budget papers said that spending on the Australian Research Council was expected to increase from $808,837,000 to $879,107,000.

National Health and Medical Research Council chief executive officer Prof Warwick Anderson said that funding for medical research through his organization would be increased from $746.1 million to $760.5 million in 2012-13.

The published Budget papers propose the carry-back of losses for up to $1,000,000 for the 2012-’13 financial year allowing companies “to carry back losses incurred in that year of up to $1.0 million so they get a refund against tax previously paid”.

The Budget papers gave as an example a business which was currently profitable and paying tax, would know that if it made investments in 2012-‘13 that initially resulted in a loss, it would get a refund of up to $300,000 of tax previously paid when the 2012-‘13 tax return was lodged.

From 2012-‘13 income year, the Government would allow small businesses to write off eligible business assets costing less than $6,500, an increase from $1,000 under the old arrangements.

The Budget said that a small business buying four items of equipment costing $6,000 each would be able to get a tax deduction of $24,000 in the first year, rather than a deduction of $3,600 under the old arrangements.

Mr Swan said that the Government would introduce simplified depreciation pooling arrangements from the 2012-‘13 income year “to save time and improve cash flow for small businesses” including the ability to claim up to $5,000 as an immediate deduction for new or used motor vehicles acquired from the 2012-‘13 income year.

The Budget papers said the Government would invest $30 million over four years to establish a Manufacturing Technology Innovation Centre to bring researchers and manufacturers together to drive innovation through new and improved industrial products and processes.

Mr Swan said there would be savings of $163.5 million in the Pharmaceutical Benefits Scheme and the Budget papers said the savings came from more competitively priced medicines, including the angiotensin II receptor antagonist therapeutic group and new indications for a number of medicines including dasatinib (Sprycel), niliotinib (Tasigna), and tocilizumab (Actemra), as they can be used in place of more expensive medicines.

The Budget said $49.7 million would be spent over four years to expand the bowel cancer screening program to Australians aged between 50 and 74 years and was expected to help detect around 12,000 cancers and adenomas each year and reduce deaths from colorectal cancer.

The Budget said $49.3 million would be spent to ensure the National Medical Stockpile was ready for any emergency.

Mr Swan said that an expected one percent company tax break for businesses related to the Mining Tax would not go ahead.

The Budget has also proposed an increase in the managed investment trust final withholding tax rate from 7.5 percent to 15 percent, effective from July 1, 2012.

The Budget papers estimate the increase would raise $50 million next year rising to $75 million in 2015-’16 and the measure would “return the withholding tax for managed investment trusts to the level of the original 2007 election commitment”.

BUDGET COMMENT

Biotech Daily

Biotech Daily welcomes the Federal Budget for marginal improvements for the sector and is grateful that there appear to be no significant cuts.

But yet again, the Federal Government demonstrates an inability to comprehend the difference between wasting money on sunset industries and investing in sunrise industries.

The Federal Government may have reduced expenditure on a traditionally bloated Defence budget, but it has made a $40 billion commitment to build more submarines, while acknowledging that the Collins class submarines were a waste of time and money.

One single Collins class submarine, that cannot submerge, and costing more than $1 billion, could provide the money for an investment fund for Australia's pivotal registration trials. Two would be better.

The $24,000 tax write-off for equipment will be welcomed by many companies, but the $5,000 grant to car companies as part of the depreciation system is a clear signal that motor vehicle sales and manufacturing, sending profits primarily to the US and Japan, are still more important to the Labor Government than the sunrise industries of biotechnology and clean technology.

The loss of a promised one percent cut in company tax is not relevant to most biotechnology companies and it is hard to value the loss of something we did not have. Certainly profitable companies and their shareholders would prefer the cut, but in itself it does not appear to be a major event for this sector. AVCAL chief executive officer Dr Katherine Woodthorpe says the increase in managed investment funds withholding tax would only apply to non-capital gains and most managed investment trusts do not have any of that type of income.

Cuts to environment programs further underline the Government's failure to invest in the manufacturing industries of the future.

The innovation sector appears to have survived another Budget, but the lack of long term investment in future industries is yet again another lost opportunity.

David Langsam
Editor

Ausbiotech

Ausbiotech says that Treasurer Wayne Swan's fifth budget was "largely a business-as-usual budget for innovation and biotechnology".

Ausbiotech chief executive officer Dr Anna Lavelle said that "in another tough budget year, innovation has been spared the rumored cuts to the R&D Tax Incentive, which were to be targeted specifically at companies with turnover over $20 million".

Dr Lavelle said the possible cuts were discussed by an independent Treasury committee and it was welcome news that the R&D Tax Incentive remained intact.

GBS Venture Partners
In a tough budget for many sectors, the government displayed an ongoing commitment to innovation, commercialization and long term investment in the knowledge economy.

The R&D Tax Credit, Commercialisation Australia and the Innovation Investment Fund program are strong programs.

We need to see what will come after the Innovation Investment Fund program which is currently in its final year, to ensure the continuing health of the venture capital sector to help Australian biotech reach its full potential.

GBS Venture Partners

Bio-Melbourne Network
One should be pleased that there were no budget cuts directly affecting the biotech sector. And we genuinely are grateful.

But at the risk of sounding facetious, where would the Government cut it from anyway? Although industry did not get the promised company tax cut in this budget, biotechnology did get the R&D Tax Incentive and Raising the Bar legislation, earlier in the year.

The Federal Minister for Small Business Brendan O'Connor deserves applause with the introduction of the loss carry-back initiative. The scheme gives some relief to small innovation businesses, particularly exporters, from the crippling effects of the high Aussie dollar.

The Australian dollar is certainly eroding profit margins from a number of our technology companies and this fundamentally undermines their sustainability and likelihood of them remaining in Australia.

The loss carry back initiative is welcome - but will it be enough?

The budget papers also announce the establishment of an Australian Small Business Commissioner. Let's network with prejudice to get someone from the innovation technologies sector to apply for this job.

Although the Government is clearly backing the clean technology sector and the Melbourne-based car industry in this budget, the creation of a $30 million Manufacturing Technology Innovation Centre to link networks with major manufacturers, small and middle-sized enterprizes, industry bodies and research organizations is creative.

This announcement is inspiring in that it may greatly enhance collaboration and encourage broader translation of technologies across traditional industry sectors.

This initiative will be able to link into the new $236 million Industrial Transformation Research Program, existing infrastructure and skills, Commercialisation Australia, for example, providing some real value particularly to the diagnostics, devices and instrumentation sector.

Michelle Gallaher
Chief executive officer
Bio-Melbourne Network

BIODIEM

Biodiem says it will investigate the synergy between its live attenuated influenza virus (LAIV) and France-based Vivalis's proprietary cell line, EB66.
Biodiem said that successful results from the investigation could be used as a basis for a new agreement between the companies to test the feasibility of development of LAIV as a vector in Vivalis proprietary cell line.
Biodiem said that terms of the agreement were not disclosed.
The company said that viral vector technology was used in vaccines to deliver immune-stimulating proteins into the body.
Biodiem chief executive officer Julie Phillips told Biotech Daily that although its virus was an attenuated influenza virus the research would further the high potential value of the technology in non-influenza vaccine applications.
Biodiem said it proposed developing the LAIV as a versatile vector or carrier technology, which could be used to create a variety of new vaccines, both therapeutic and preventative.
The company said that the proposed vector would be developed to have the additional advantages of a good safety profile and low toxicity, as the virus backbone was already weakened, excellent virus characterization from extensive prior work and the ability to be customized to target particular diseases.
Biodiem said that the collaboration involved Vivalis confirming that Biodiem's LAIV strains grew satisfactorily in its proprietary cell line EB66 and examining any effects on the virus' characteristics.
The company said that during this stage, long-term collaborator and LAIV developer, the Institute of Experimental Medicine in St Petersburg, would send an LAIV expert to work on-site with Vivails in France.
Biodiem said the initial program was expected to take up to 10n weeks and following successful demonstrations of growth and productivity, Biodiem would look to negotiate another agreement with Vivalis regarding a longer-term research project aimed at developing a stable LAIV vector technology incorporating EB66 as a base platform for growth.
"Vivalis is an ideal vaccine development partner, with a strong commercial mindset, a history of successful partnerships and great technology in the internationally established EB66 cell line," Ms Phillips said.
Vivalis said that advancing the EB66 platform into novel areas was an objective maintained from the initial launch of the platform.
Biodiem was unchanged at 8.3 cents.

GENETIC TECHNOLOGIES

Genetic Technologies has granted certain non-exclusive rights to a number of patents relating to non-coding DNA to Geneseek Inc of Lincoln, Nebraska.
Genetic Technologies said that Geneseek was a subsidiary of Neogen Corp and a counterparty to the third formal patent assertion suit filed against 10 companies in the US District Court for the District of Colorado and the fourth counterparty in that case to settle.
The company said that the commercial terms were covered by formal confidentiality provisions and could not be disclosed and that discussions with other parties are ongoing and progressing.
Last year, Genetic Technologies filed the suit, asserting infringement of its primary non-coding patent against 10 companies (BD: May 26, 2011).
Genetic Technologies was up 0.2 cents or 2.5 percent to 8.2 cents.

HEARTWARE

Heartware says it has completed enrolment for its pivotal destination therapy clinical trial evaluating its ventricular assist system in patients with end-stage heart failure.
Heartware chief executive officer Doug Godshall said that completing enrolment in “the largest head-to-head ventricular assist device clinical trial to date, is a major achievement and we look forward to following this destination therapy patient population to primary endpoint over the next two years”.
Mr Godshall said that 50 US hospitals were involved in the study and more than 2,000 end-stage heart failure patients had received the Heartware ventricular assist system.
Heartware said that the trial was a randomized, controlled, unblinded, multi-center clinical trial to evaluate the use of its ventricular assist system as a destination therapy.
The company said that the non-inferiority study enrolled 450 patients with end-stage heart failure who had not responded to standard medical management and who were ineligible for cardiac transplantation.
Heartware said that patients were randomly selected to receive either the Heartware ventricular assist system or, as part of a control group, any alternative left ventricular assist device approved by the US Food and Drug Administration for destination therapy, in a two-to-one ratio.
The company said that each patient would be followed to the primary endpoint at two years, with a subsequent follow-up period extending to five years post implant.
Heartware said the primary endpoint of the trial was survival at two years, defined as alive on the originally implanted device without a debilitating stroke, transplanted or explanted due to patient recovery.
The company said the secondary endpoints include adverse events such as bleeding and infection, as well as functional status, hospitalization, assessment of neuro-cognitive function and patient quality of life.
Heartware said that its ventricular assist system pre-market approval application was under FDA review for a bridge-to-transplant indication and last month the Circulatory System Devices Panel voted in favor of the device (BD: Apr 26, 2012).
Heartware was up one cent ot 0.5 percent to $2.18.

CATHRX

Cathrx hopes to raise $12 million to cover a two year program and delist from the ASX, ahead of selling the business.
Cathrx executive chairman Denis Hanley told an investor teleconference the company was in discussion with a number of potential underwriters and buyers.
Mr Hanley said that the low liquidity in Cathrx shares on the ASX meant that the company’s market valuation varied with very small share movements.
Mr Hanley said that the company needed to demonstrate its new reprocessable cardiac catheter manufacturing and business model in the UK and Malaysia to the potential buyers (BD: Mar 8, 2012).
He told the teleconference that the company had $1,211,000 at March 30, 2012 with a reducing burn of $329,000 in March and $890,000 for the year to date.
Mr Hanley said the company had a tax rebate expected by the end of 2012 and a $1 million line of credit.
Cathrx was unchanged at 2.5 cents.

BLUECHIIP

Bluechiip says it has engaged the US-based Plexus Corp to manufacture its commercial-ready Matchbox reader hardware.

Bluechiip said the contract with Plexus complemented the January 2011 agreement with Geneva-based ST Microelectronics to manufacture the tracking tags for cryogenic sample tracking.

The company said that the Matchbox reader, which came pre-loaded with Bluechiip's proprietary Stream sample tracking software, read the Bluechiip tags in sample storage containers such as tubes and vials, as well as the racks used to store the samples, normally stored in ultra-low temperature freezers and tanks in bio-banking facilities.

Bluechiip said that Plexus specialized in manufacturing complex, high-technology products for technology companies.

Bluechiip fell two cents or 10 percent to 18 cents.