



Biotech Daily

Wednesday May 13, 2009

Daily news on ASX-listed biotechnology companies

BUDGET 2009 SURPRISES SECTOR: FAR MORE THAN EXPECTED

**BIOTECH SPENDING SUMMARY
MARC SINATRA'S BIOGUIDE
INNOVATION MINISTER SENATOR KIM CARR; WHITE PAPER
AUSBIOTECH; BIO-MELBOURNE NETWORK**

- * ASX DOWN, BIOTECH UP:
BENITEC, SUNSHINE UP 20%, CYTOPIA DOWN 23%**
- * NANOSONICS SUBMITS DISINFECTION SYSTEM FDA APPLICATION**
- * BECTON DICKINSON - TYRIAN TB TEST FEE AND RESEARCH FUNDING**
- * DELAYS TO IM MEDICAL ACQUISITION OF RADIOLOGY BUSINESS**
- * CORRECTION: PROBIOMICS**
- * CEPHALON NEARS 40% OF ARANA**

MARKET REPORT

The Australian stock market fell 0.54 percent on Wednesday May 13, 2009 with the S&P ASX 200 down 21.1 points to 3,856.1 points.

Seventeen of the Biotech Daily Top 40 stocks were up, 14 fell, six traded unchanged and three were untraded.

Benitec and Sunshine Heart were best, up 20 percent to 3.6 cents and six cents respectively, followed by Nanosonics up 16.1 percent to 36 cents, Living Cell up 12.8 percent to 22 cents and Tyrian up 11.4 percent to 3.9 cents.

Genetic Technologies climbed 10 percent; Acrux and Tissue Therapies were up more than five percent; Avexa was up 4.8 percent; Biota was up 3.65 percent; Cellestis, Clinuvel and Phylogica rose more than two percent; with Cochlear, Heartware, Mesoblast, Pharmaxis and Universal Biosensors up more than one percent.

Cytopia led the falls, down 2.8 cents or 23.3 percent to 9.2 cents with 40,000 shares traded, followed by Bionomics and Phosphagenics down more than six percent. Genera, Polartech and Sirtex fell more than four percent; Alchemia, Psivida and Viralytics were down more than three percent; Chemgenex and Peplin shed more than two percent; Novogen fell 1.1 percent; with Arana, CSL and Progen down less than one percent.

[FEDERAL BUDGET 2009 SPECIAL EDITION](#)

With expectations set fairly low, the Federal Labor Government's second Budget appears to have delivered far more than the sector's call for \$600 million.

Budget promises in Treasurer Wayne Swan's address last night include:

- * \$1.4 billion a year through the 45 percent research and development tax credits;
- * funding for "world class hospital research and innovation";
- * \$703.1 million for universities for research across all disciplines;
- * \$196.1 million for four years and \$82 million a year indefinitely for the Commonwealth Commercialization institute;
- * \$504 million for biotechnology infrastructure in the Super Science Initiative; and
- * \$27.2 million for 100 research grants.

[How The 45 Percent Tax Credit Works](#)

Innovation Minister Senator Kim Carr's office says the 45 percent refundable tax credit is equivalent to a 150 percent tax concession with more than 5,500 smaller firms expected to benefit.

The tax credit is available at a 40 percent rate for companies with a turnover above \$20 million and foreign-owned companies.

"They will receive a cash refund of 45 percent of their research and development spending when they file their tax return. It doubles the tax incentive for smaller firms, restoring support to the level that prevailed before 1996

"Small companies can access the credit whether they are in tax profit or tax loss."

The measure assists innovative firms in biotechnology, information technology, environmental and medical-technical companies.

"The Government is responding to the immediate affect of the global recession on innovative firms by raising the amount of research and development spending small firms can claim under the current research and development Tax Offset from \$1 million to \$2 million for 2009-'10," the Minister's office said.

Senator Carr's office said the Commercialising Emerging Technologies (Comet) fund was "not trimmed or changed in any way".

[BIOGUIDE BRIEF NOTE: BUDGET 2009](#)

Having learned a fortnight ago, that for the first time a group of biotechnology industry bodies would have personnel in this year's Budget lock-down, I felt some optimism and, after last night, this proved well-founded.

Three components of the Budget could have a major impact on our industry.

The first and biggest is the introduction of a system of R&D tax credits of 40% or 45% which should greatly simplify the tax framework. Importantly, according to Kim Carr, "companies can access the credit whether they are in profit or not".

For a lot of small companies, this means they will see a benefit before they reach that almost mythical state called profit. In my opinion, this new tax system should be very, very good for our industry and the companies within it.

The second is the establishment of the Commonwealth Commercialisation Institute, which will aim to help commercialize "the best ideas developed by our universities and publically funded research organizations". The institute will have \$196.1 million of funding over the first four years as well as \$82 million a year after that.

This new institute is an attempt to consolidate and give critical mass to the work of individual commercialization arms of Australia's universities and other institutions. With many of the details of the institute still to be decided, it is difficult to determine what the benefits and risks will be. Done well, this new institute could be very good for the biotechnology industry. Done, poorly it could cost a lot more than the money put into it.

The final section of the Budget is the Future Industries section of the Super Science initiative, which will see \$504 million invested research infrastructure for biotechnology, nanotechnology and information and communications technology. Of particular interest to drug development companies will be the Government's \$35 million commitment to enhance the countries treatment development capabilities.

I have criticized the Government for being too infrastructure focused in the past on the basis that big toys are only useful if you have the minds and skills to develop products from them. Given the Government has addressed the latter two areas in this Budget, this level of infrastructure investment seems appropriate.

Health and education are two other areas that will benefit from this Budget, both of which should have positive flow-on effects for the biotechnology industry.

Overall, the Budget indicates that the Rudd government has not given up on innovation like many had feared after the last Budget and the mix of initiatives are significant and appear well thought-out.

I would still have liked to see some initiatives aimed at later stage commercialization in biotechnology, the end of the process we don't yet have a lot of experience in. But, the current Budget will still do nicely, thank you.

Marc Sinatra, analyst

[Innovation Minister Senator Kim Carr](#)

Through a media officer Senator Carr told Biotech Daily: "The budget package delivers strong benefits for the biotechnology sector. It is one of our industries of the future."

"Our new R&D Tax Credit, valued at over \$1.4 billion per annum, will provide much needed support for biotechnology research and development activity," Senator Carr said. He said the 45 percent refundable tax credit was available for Australian-owned firms turning over up to \$20.0 million a year from 2010-'11.

"It will help many biotechnology companies and is the equivalent to a 150 per cent tax concession," Senator Carr said.

"It doubles the base tax incentive for smaller firms, restoring support to the level that prevailed before 1996 - with the added advantage that companies can access the credit whether they are in tax profit or tax loss," he said.

"Because such a significant change cannot be introduced immediately, as an interim measure, the Commonwealth will raise the amount of research and development spending small firms can claim under the R&D Tax Offset from \$1 million to \$2 million in 2009-'10.

"Our new National Enabling Technologies Strategy supported with \$38.2m over four years, will assist Australian industry in the responsible take-up of enabling technologies, including both biotechnology and nanotechnology," Senator Carr said.

"And our new Commonwealth Commercialisation Institute, attracting \$196.1 million over four years, will provide assistance with the commercialization of R&D, taking ideas to market and to help innovative young enterprises access private capital," he said.

"The Review of the National Innovation System argued for a more coordinated approach, with support to match 'the various identifiable stages of an innovative firm's life'," he said.

"The Institute will bridge a critical gap by supporting innovative firms to access the expertise and capital they need to cross the chasm between research and commercialization."

"The Institute will help to shake loose additional private sector capital to leverage Commonwealth support," Senator Carr said.

He said the Super Science Future Industries package, part of this Government's \$1.1 billion Super Science Initiative, provided \$504 million to fund infrastructure and facilities for biotechnology to advance disease prevention and food security including: facilities for the study of genes, proteins and cell products; national networks to support drug discovery, novel cell therapies, the development of nano-medicines and integrated population health solutions; a European Molecular Biology Laboratory Partner Laboratory at \$18 million to provide access to cutting-edge expertise underpinning developments in biotechnology; and an integrated online biodiversity knowledge base.

"Biotechnology companies will also be able to continue to access the Business Investment tax break.

"The \$703.1 million to increase the research capacity of the nation's universities will have significant impact across research in all areas," Senator Carr said.

[Powering Ideas](#)

Separately, Senator Carr said the Government outlined its innovation agenda for the next decade in a White Paper entitled 'Powering Ideas: An Innovation Agenda for the 21st Century' which can be downloaded from <http://www.innovation.gov.au/innovationreview>.

[Ausbiotech](#)

Ausbiotech chief executive officer Dr Anna Lavelle told Biotech Daily the Budget was “fantastic for the middle term but not in the immediate term”.

“In this grim environment with a tough budget it looks like innovation, science and research has been a big winner,” Dr Lavelle said.

She said Ausbiotech was hoping for immediate assistance for small companies which was not provided by the Budget but the 45 percent Tax Credit measure was very valuable.

“It’s the biggest change in the tax system since the introduction of the tax concession system itself,” Dr Lavelle.

She said that assuming a 30 percent tax rate for every \$100 spent on research and development companies would receive \$15 cash back.

She said that it would help companies if the payments were made quarterly like the Business Activity Statement for the Goods and Services Tax, rather than having to wait until the end of the year for the rebate.

Dr Lavelle said the Government had allocated \$8.5 billion to all of science, education and innovation and 25 percent increase over last year.

[The Bio-Melbourne Network](#)

The Bio-Melbourne Network chief executive officer Michelle Gallaher told Biotech Daily that the budget contained direct funding for the sector, an array of measures that would have long term knock-on benefits along with an incalculable contribution through funding health and medical research along with higher education expenditure.

“I think the budget last night is a clear recognition of the value now and in the future of the biotechnology and research sector,” Ms Gallaher said. “I’m very happy with it.”

Ms Gallaher said there were “significant knock-on effects to biotechnology over the coming three to six years” including indirect funding through major investment in the sector’s research partners.

She said the Budget invested in intellectual capital including at PhD and early post-doctorate level and Technical And Further Education (TAFE).

Ms Gallaher said TAFE funding had a direct effect through relevant, timely and responsive courses training laboratory technicians animal laboratory technicians and research assistants along with courses in biotechnology processing and manufacturing.

Ms Gallaher said there would be knock-on effects through a 10 percent increase in funding to the Australian Postgraduate Awards along with the 100 Super Science Fellowships for early post doctorate researchers for three years, of which many would be granted to related fields of medical agricultural and industrial.

“The Valley of Death is still there, but Comet has survived as has the Export Marketing Development Grant which is especially useful to device companies,” Ms Gallaher said.

She said the marketing grant rebated all development costs including attending conferences and international meetings.

Along with the \$83 million Innovation Investment Follow-on Fund announced in March (BD: Mar 18, 2009) there was \$35 million for preclinical testing facilities.

Ms Gallaher said the most exciting part of the Budget for Biotech was the Commonwealth Commercialization Institute which would help commercialize ideas developed from universities and public research institutes as well as support innovation from potentially rapid growth to take ideas to market.

NANOSONICS

Nanosonics has instructed Safis Solutions, to submit its 510(k) application to the US Food and Drug Administration for the Trophon EPR and Nanonebulant consumable.

Nanosonics said to meet the FDA requirements, the submission required further extensive microbiological testing of the Trophon environmental probe reprocessor (EPR) device.

The company said it had appointed Safis Solutions as its US-based consultant to coordinate contact with the FDA during the application process, with the FDA targeting an initial review and feedback within 90 days from lodgment.

Prospective distribution partners estimate the size of the US market for the Trophon device to be more than \$200 million and Nanosonics said it was "in advanced discussions with potential distributors for the US and Canada".

Nanosonics said it had regulatory approval for the Trophon EPR and consumable in Europe, Australia and New Zealand.

The company said it was on track for the controlled roll-out of the Trophon EPR and consumables in Europe by July, 2009 with initial sales in France, Germany and the UK.

Nanosonics said it had begun its Australian sales program with successful tenders for installations in public hospitals and private clinics.

Support for the marketing program has been assisted by the Trophon EPR being specified in two Australian state government tenders for the provision of disinfection technology.

The company said it had developed pre-commercial prototypes of additional devices and was in discussions with potential partners to fast track market entry.

Nanosonics was up five cents or 16.1 percent to 36 cents with 1.1 million shares traded.

TYRIAN DIAGNOSTICS

Tyrian Diagnostics says Becton Dickinson and Co will pay an undisclosed upfront fee and fund nine months research on its point-of-care tuberculosis test.

Tyrian said Becton Dickinson had agreed to an extended option period under the current agreement allowing further feasibility studies of the suitability of Tyrian's tuberculosis (TB) protein markers for the development of rapid diagnostic tests to detect active TB disease.

Tyrian said it would receive an option fee from Becton, Dickinson, who would be granted research and development rights to conduct further feasibility studies on a point-of-care TB test using Tyrian's biomarkers.

Tyrian said Becton, Dickinson would fund this next stage of research which could take up to nine months.

Tyrian said it retained the rights to use its TB biomarkers to develop and commercialize a molecular TB test, which it intended to explore in collaboration with a suitable partner.

Tyrian chief executive officer Dr Jenny Harry said Becton Dickinson had access to "cutting edge technology and the necessary expertise" to develop her company's TB biomarkers.

"Assuming that appropriate sensitivity and specificity is achieved in these studies, we believe that there is an exciting opportunity for a rapid, cost-effective and easy-to-use diagnostic to address a market gap for diagnosis of active TB," Dr Harry said.

In January 2009, Tyrian announced the completion of the fourth milestone of its feasibility study under its collaboration agreement with Becton Dickinson to assess the suitability of Tyrian's TB protein markers for rapid diagnostic tests (BD: Jan 16, 2009).

Tyrian's lead TB biomarker was detected in clinical strains of the bacteria responsible for TB as well as in clinical sputum samples.

Tyrian said the next stage was Becton Dickinson studying its technology to achieve the levels of sensitivity and specificity for an effective point-of-care diagnostic.

Tyrian was up 0.4 cents or 11.4 percent to 3.9 cents.

IM MEDICAL

IM Medical says there have been delays to its proposed acquisition of the radiology and imaging business of the Mark Scott Group trading as Melbourne Specialist Imaging. IM Medical said there were delays in the finalization of the independent expert's report and other documentation and consequently the notice of general meeting and explanatory memorandum was not likely to be submitted to shareholders until the end of May 2009. Separately the company said that following the introduction of the pre-paid Intelliheart test through the Pulse Pharmacy Group in Victoria, it would partner the Healthwise Pharmacy Group in introducing the Intelliheart test into pharmacies in regional Victoria. IM Medical said the trial would begin in four pharmacies in Warrnambool and Colac. The company said Healthwise Pharmacy had 13 pharmacies in regional Australia, 11 in Victoria. IM Medical closed unchanged at 0.5 cents with 25.0 million shares traded.

PROBIOMICS

Prof Ron Penny who was co-author of 'Use Of Probiotic Bacteria As An Adjuvant for Influenza Vaccine' is the medical director of Good Health Solutions and not the chief medical director as reported. The mistake was made by a sub-editor. Probiomics was unchanged at 0.9 cents.

ARANA

Cephalon International Holdings increased its substantial shareholding in Arana from 86,165,574 shares (37.85%) to 89,463,066 shares (39.30%). The change was through an increase in takeover acceptances (BD: Feb 27, Mar 2, 2009). Cephalon told investors on May 11, 2009 that it would not increase its offer of \$1.40 a share if more than 50.1 percent of acceptances were received by June 1, 2009 and \$1.45 if more than 90 percent of acceptances were accepted. Those prices will be reduced by five cents to compensate for a five cent special dividend paid by Arana. Cephalon said Arana's independent directors had notified their acceptances for the offer. A Cephalon spokesman told Biotech Daily that the directors were chairman Robin Beaumont and Chris Harris. Cephalon needs to receive acceptances for a further 10.8 percent of investor acceptances over the coming 13 trading days, unless to further amends its takeover bid. Arana fell one cent or 0.74 percent to \$1.345.