

5 July 2011

Dr Anna Lavelle, CEO of AusBiotech responds to questions from BioSpectrum Asia:

1. Which are the major growth areas in Australian biotech industry? Who are the key players in the market.

Australian biotechnology has been strong in the sphere of global biopharmaceuticals, but the world of biotech has broadened its horizons substantially in recent years. The emerging trends of foodtech and cleantech have gained momentum, and the medtech sector is surging forward, to follow in the footsteps of medtech industry pioneers, Cochlear and ResMed.

Medtech

The medtech or medical technology industry is growing rapidly not only in Australia but around the world, with annual revenues forecast to be over (USD) \$288 billion in 2011.

Driving the demand in medical devices in Australia, is one of the world's fastest ageing populations. By 2050, over 30% of the population are estimated to be over 65 years of age and the '85 or older' age group is the fastest-growing segment.

Australia has seen its medtech sector advancing vigorously for some years and now has an established community of companies, particularly in Victoria and New South Wales (NSW) working on diagnostics, joint replacements, artificial hearts and heart stents, as well as implants like the cochlear implant.

Industry success stories, ResMed, maker of devices to treat sleep disorders, and bionic ear pioneer, Cochlear, now have a market capitalisation of more than (AUD) \$5 billion and almost \$4 billion respectively. These are the 'majors' of the estimated group of more than 1,000 companies that make up Australia's medtech industry. The majority of companies are at the start-up end of the spectrum and employ fewer than 20 people. Around 10% of the sector now employs over 100 people.

Industry turnover in Australia is over \$A 6.5 billion annually, with revenue from local manufacturing more than tripling, from \$A898 million in 2003-04 to \$A3.2 billion in 2010-11. There are at least 17,500 people employed by 1,890 enterprises in the sector, generating more than \$A1.1 billion in wages. This reflects the strong growth since 2003-04 when there were only 710 enterprises employing 4,800 people.

The industry is advancing rapidly, using research developments to facilitate innovations in the biomedical sphere. An increasing convergence of technology platforms has resulted in greater collaboration across the disciplines of biomedical, electronic and mechanical engineering, nanotechnology, ICT and software development to develop the next generation of medical bionics.

Foodtech

Food and dietary components that provide health benefits beyond basic nutrition are commonly referred to as food technology, foodtech or 'functional foods' and encompasses nutraceuticals.

“Functional foods are considered to be any food or food component that may provide demonstrated physiological benefits or reduce the risk of chronic diseases, above and beyond basic nutritional functions.” (Invest Australia, 2004)

Nutraceuticals are regarded as a subset of functional foods and defined as: “Bioactive chemicals derived from foods but taken as supplements at much higher concentrations than diet alone could provide”. (Scientific American, 2008)

Australian and New Zealand nutrition industry represented around 1.4% of the global nutrition market, which is valued at more than \$A 208 billion – with growth predicted at up to 300% per annum.

The rise of foodtech is thought to be due to increasing concern amongst consumers about debilitating and chronic illnesses and diseases of ageing such as Alzheimer’s disease, cancer, diabetes, heart disease and osteoporosis.

Public awareness of the link between diet and health has accelerated growth in the functional food industry. Health authorities are increasingly acknowledging the importance of functional elements in foods, such as plant sterols role in improving health, lowering cholesterol and preventing heart disease.

The CSIRO has recently launched a new barley “supergrain” that contains twice the dietary fibre of regular grains, four times the resistant starch - a type of fibre which promotes better bowel and digestive health - and has a low glycemic index. BARLEYmax took over 12 years to develop and is now being used in a range of Australian-made breakfast cereals.

More recently foodtech has come to the fore in discussions about food sustainability for a rapidly expanding population. With the world population due to reach nine billion by 2050, a recent report from the British Government’s Foresight group, ‘Global Food and Farming Futures’ said: “Multiple threats are converging on the food system, including changes in the climate, competition for resources such as water supply and energy, and changing consumption patterns providing considerable challenges to sustaining the world’s food supply.”

The Bill and Melinda Gates Foundation has for some years provided funding in support of food technologies, including genetic modification in developing solutions to food-supply issues and improving nutrition.

The Foundation says already “Two billion people in the developing world are malnourished, with diets lacking essential vitamins and minerals. The health consequences are dire, especially for children. One promising solution is helping small farmers grow nutritionally enhanced staple crops like sweet potato, rice, and cassava.”

Two grants, together worth \$A17.7 million were recently awarded to enhance staple crops to fight malnutrition in Africa and Asia. Both grants will be used to enhance the food staples: rice with beta carotene for vitamin A: and cassava with beta carotene, protein and iron. Both these foods are important sources of kilojoules, but with little nutritional value.

Cleantech

The development of cleantech has been gradual, patchy and slow, following the rise of concern for the environment, such as global warming. Cleantech refers to technologies that address environmental concerns, including renewable energy, energy storage, biofuels, cleaner fossil

fuel processes, water purification and waste water treatment, recycling, energy efficiency, pollution reduction and advanced materials, such as nanotechnologies.

According to Cleantech Ventures: “Clean technologies are emerging as the enablers of the modern industrial society, the next and necessary wave of venture innovation in a resource-constrained world.”

The Australian Cleantech Review 2011 reviewed 767 Australian cleantech companies - the majority of companies operating in this sector. The companies had combined revenue of over \$A 22 billion, placing the sector at about half the size of the national construction industry in terms of contribution to GDP. The sector employs over 25,000 people and was involved in capital transactions totaling \$A 1.4 billion during the 2010 calendar year in 214 separate deals.

Perhaps the most relevant component of cleantech is the biofuels sector, which is seeing significant advances in developing alternative fuels from waste.

According to the Biofuels Association of Australia, biofuels represent an immense growth area around the world and have an important role to play in displacing the types of fuels the world has used in the past.

Transport is currently dependent on finite fossil fuels such as oil and petroleum for its energy needs, but because transport is the third largest emitter of greenhouse gases it makes sense to develop ways in which biofuels can significantly reduce the carbon emissions, by moving towards more renewable and sustainable fuels.

New technologies on the horizon don't use food crops but the fibrous woody parts of plants, known as lignocellulose. These technologies can create biofuels from feedstocks such as garden waste, forest and sawmill waste, or even plantations dedicated to energy production.

Biofuels are moving on from first generation technologies, those using sugar or starch to produce ethanol, and waste oil to produce biodiesel, to second generation biofuels that use non-food biomass, such as lignocellulose to make biodiesel and ethanol.

Through the AusBiotech-managed National Collaborative Research Infrastructure Strategy (NCRIS) program, the Commonwealth and State Government partners have enhanced Australia's capacity to produce biofuels and other products derived from non-food biomass in pre-commercial quantities.

Two pilot and demonstration scale manufacturing facilities have been established, one for the conversion of lignocellulosic biomass to ethanol, and the other for the production of biodiesel from microalgae:

- The Queensland University of Technology's (QUT) [Mackay Renewable Biocommodities Pilot Plant Facility](#) is manufacturing bioethanol and high value biocommodities from cellulosic biomass.
- The [NCRIS Photobioreactor Facility](#) at the South Australian Research and Development Institute (SARDI) is producing biodiesel and high-value products from microalgae.

2. How do you think the Intellectual Property Laws Amendment will affect the development of biotechnology research in Australia?

AusBiotech supports 'Raising the Bar'

AusBiotech has welcomed a legislative Bill that has been introduced into the Australian Parliament today - The Intellectual Property Laws Amendment (Raising the Bar) Bill 2011.

AusBiotech confirms its support in general for this package of intellectual property reform developed by IP Australia and contained in the 'Raising the Bar' Bill. Specifically, AusBiotech is in favour of a broad research use exemption from patent infringement becoming enshrined in Australia's patent law so this country's researchers and industry may be confident as they strive to innovate.

In its recent submission to the Senate Inquiry into the Patent Amendment (Human Genes & Biological Materials) Bill 2010, AusBiotech stated its belief that the thresholds for patentability should be properly set and rigorously applied across all forms of invention, ie: in a technology-neutral manner. AusBiotech has publicly and strongly opposed the Patent Amendment (Human Genes & Biological Materials) Bill 2010, as it completely fails to address any of the community's valid concerns and threatens scientific research and development on biological materials.

AusBiotech is instead in favour of the Government's 'Raising the Bar' Bill which, when taken together with the erudite recommendations from the Australian Law Reform Commission 1999 report, the Senate Inquiry into Gene Patents (2010) and the Advisory Council on Intellectual Property 2010 review will deliver the solutions to address the issues identified by clinicians, researchers, industry and the community.

AusBiotech strongly encourages the Australian Parliament to support the Bill so that the many consequential benefits of the law reform can be effected.

Two years of consultation and deliberation that has resulted in the "Raising the Bar' Bill, will guarantee a strengthening of Australia's IP management system.

3. Can you also elaborate on tax credit on RnD and how it will affect development and investment? What is the future of biotechnology research and market in Australia?

Following a lengthy and sustained campaign, the biotechnology community is celebrating news that the much-needed Research & Development (R&D) Tax Credit will be delivered imminently, providing a major boost for innovative biotechnology companies and spill-over benefits for the community from biotechnologies.

Treasurer, Wayne Swan and Senator Kim Carr, Minister of Industry, Innovation, Science and Research have announced in a joint media release an agreement that will see the Tax Credit

legislation pass in the August sitting of the Senate and be effective from 1 July 2011 – thereby delivering the Tax Credit to provide a meaningful incentive and “landmark reform” for R&D in Australia.

Start-up innovation companies, especially biotechnology companies trading in loss, are set to be the big winners from the Tax Credit’s 45% refundable component, and the legislation will also benefit large innovative companies by reducing the cost of conducting eligible R&D activities in Australia by up to 10%, making Australia a more competitive location for conducting biomedical and pharmaceutical R&D.

AusBiotech and its membership have been strong and unwavering advocates for the move to a tax credit since its recommendation by Dr Terry Cutler in the Innovation Review of 2008, as good for the biotechnology sector and for innovative Australian companies generally – and therefore welcome the long-awaited news with enthusiasm.

The two Bills that make up the legislation are awaiting debate in the Senate, more than two years after the R&D Tax Credit was announced in May 2009. Since the announcement of the policy, AusBiotech has made four substantive submissions on the R&D Tax Credit and produced 11 case studies on how the incentive will benefit R&D in Australia, after extensive consultations with members.

This is the result of more than two years of advocating, consultation and working toward a good policy for innovation, however the work is not done yet. The Bill still needs to officially pass into law, and we support its passage and eagerly await the moment.

The biggest winners from the Tax Credit will be those companies in their early stages with turnover of less than \$20million with no commercial production yet, which are able to cash out the refundable credit if in tax loss. The Tax Credit will provide greater incentives across the whole innovation industry, as well as vital support for start-up and small biotechnology companies, which is well targeted to increase R&D expenditure among these companies.

AusBiotech also welcomed news that the Government, with support from the Greens, will pursue an amendment to the Tax Credit program to provide quarterly payments of cash refunds, instead of annual payments, as recommended in AusBiotech’s February 2010 submission in response to the ‘exposure draft’ of the Tax Laws Amendment (Research and Development) Bill 2010.

AusBiotech has always advocated for payments on a quarterly basis to assist companies manage cash flow. A survey conducted by AusBiotech as part of a series of tax credit briefings in July 2009, indicated the timing of the receipt of tax credit payments (i.e. quarterly or annually) will be a critical factor in its value as an incentive for additional R&D activities.

The crossbench support will mean the implementation date is 1 July 2011; and a provision will be introduced to make quarterly payments available to firms in tax loss from 1 January 2014.

Because the Bills have a degree of retrospectivity, to give business certainty in their planning, the crossbench Senators have agreed to an early announcement of their intent to support the Bill. This allows time for discussions with intermediaries such as industry organisations and tax consultants about how the Tax Credit will operate.

We are heartened by the news that the Tax Credit is about to become a reality and the intention to pursue quarterly payment demonstrates that the Government's willingness to listen to small innovation companies and the Greens' genuine support for legislation that will enhance R&D, and in particular legislation that would stimulate additional R&D in small and medium companies."

The passing of the Tax Credit legislation will realise the recommendations of the 2010 Senate Inquiry that recommended the Tax Credit be implemented as soon as possible, as well as the proposal in the 2011 Australian Business Foundation report by Dr Nicholas Gruen of Lateral Economics, that the new R&D Tax Credit scheme should be passed into law.

The report said the further delay in passing the legislation "would not only delay the increases in R&D investment from small firms that could be expected from the changes, but could also retard investment in R&D by smaller firms, even if it were viable under the current regime." (2011: *The BERD in the hand: Supporting Business Investment in Research and Development.*)

4. What are the factors that will attract investors from other countries to invest in Australia?

The R&D Tax Credit is the most significant positive news that the industry has had for a number of years and for small biotech companies it's going to mean significant difference to the R&D program, which is likely to unleash a new wave of biotech investment in Australia.

Biotech companies and their research programs will be significant beneficiaries of this tax reform, and we expect to see a fresh flow of investment. Private investment will be encouraged by the ability to leverage their investments, while reduced increasing speed will reduce risk and cost, making a good equation for both the companies and private investors.

The new tax credit will inject significant new funds into the industry and that will stimulate new investment.

They will be able to begin their clinical trials earlier, they will be able to spend more money on R&D over time and hopefully they will be able to get their end goal of entering the market faster than before.

The Tax Credit will make a difference for hundreds of biotechnology companies as well as hundreds of cleantech, medtech, agbio and ICT companies, including a significant number of the 100+ ASX-listed companies. All biotechnology companies will benefit from the reform to some degree and the majority will benefit dramatically.

A biotechnology company's R&D program is its fundamental reason for being, and the Tax Credit therefore speaks to its core business activities - the production of intellectual property -

which ultimately flows on to new treatments, diagnostics and other life-changing and saving solutions.

A biotechnology company with a turnover of under \$20 million, that invests several million dollars in R&D, will receive a cash refund or credit for 45 cents in every dollar, assuming the entire expenditure is directed to core R&D.

Given biotechnology's unique business model, where millions of dollars (often more than a billion) are needed to progress through the clinical trial process, achieve regulatory approval and commercialise a product, this Tax Credit will provide vital cash flows for pre-revenue companies and significant incentive and savings for others.