



Biotech Daily

Wednesday May 15, 2013

Daily news on ASX-listed biotechnology companies

- * **ASX DOWN, BIOTECH UP: IMPEDIMED UP 25%, ANTISENSE DOWN 10%**
- * **FEDERAL BUDGET: INNOVATION UNTOUCHED; NHMRC, ARC FUNDING UP**
- * **COMMENT: BIOTECH DAILY, GBS, NORTON ROSE, MEDICINES AUSTRALIA
- AUSBIOTECH, BIO-MELBOURNE NETWORK**
- * **VICTORIA OPENS AUSMEDTECH WITH \$1m GRANTS**
- * **MESOBLAST STEM CELLS EFFECTIVE FOR AMI IN SHEEP**
- * **PRIMA RAISES \$5m OF HOPED FOR \$15m**
- * **NEUREN PLEADS SCHULTZ TO ASX 66% QUERY**
- * **ISONEA PLEADS SCHULTZ, PRESENTATIONS TO ASX 27% QUERY**
- * **BIONICHE SHAREHOLDER GROUP 2nd MEETING REQUISITION**
- * **MESOBLAST CHIEF EXECUTIVE PROF SILVIU ITESCU DILUTED TO 22%**
- * **SCOTT WARD REPLACES IMPEDIMED DIRECTOR MARTIN KRIEVALDT
- TO LOSE DR MEL BRIDGES IN NOVEMBER**
- * **ST VINCENT'S FORUM 'UNLEASHING INNOVATION' - REMINDER**

MARKET REPORT

The Australian stock market fell 0.56 percent on Wednesday May 15, 2013, with the S&P ASX 200 down 29.3 points to 5,191.7 points. Seventeen of the Biotech Daily Top 40 stocks were up, 12 fell, seven traded unchanged and four were untraded.

Impedimed was the best, up 1.4 cents or 25 percent to seven cents with 735,600 shares traded. GI Dynamics, Neuren and Universal Biosensors climbed more than nine percent; Prana was up 7.0 percent; Allied Health, Osprey and Reva were up more than five percent; Starpharma was up 4.1 percent; Bionomics and Optiscan were up more than three percent; Genetic Technologies, Nanosonics, Prima and Viralytics rose more than one percent; with CSL, Heartware and QRX up by less than one percent.

Antisense led the falls, down 0.1 cents or 10 percent to 0.9 cents, with 317,768 shares traded. Cellmid lost 6.45 percent; Phylogica fell five percent; Patrys and Pharmaxis were down more than three percent; Acrux, Alchemia, Atcor, Avita, Mesoblast and Sirtex shed one percent or more; with Clinuvel and Cochlear down by less than one percent.

FEDERAL BUDGET

The Federal Budget delivered by Treasurer Wayne Swan last night appears to be positive for the biotechnology sector.

A spokesperson for the Minister for Innovation Greg Combet told Biotech Daily: "In a tough Budget environment, there are no cuts to the Innovation Investment Funds, Commercialisation Australia and the 45 percent refundable [research and development] tax offset in tonight's 2013-'14 Budget."

The Federal Government said there was a new commitment of \$135.3 million over five years in the 2013-'14 Budget for Australian Research Council Future Fellowships, providing 150 more fellowships and building on the original \$844.1 million investment. The National Health and Medical Research Council chief executive officer Prof Warwick Anderson said that funding for health and medical research, through the NHMRC's Medical Research Endowment Account, increased from \$689.3 million in 2012-'13 to \$771.2 million in 2013-'14, and was forecast to increase to \$859.9 million in 2014-'15. Prof Anderson said there was an extra \$1.3 million in funding, comprising \$700,000 for clinical trials reform and \$600,000 to fund research for a rheumatic fever vaccine.

Mr Combet's spokesperson told Biotech Daily that the Government announced the successful fund managers for \$100 million in the fourth tranche of the third round of the Innovation Investment Funds (IIF) in March and committed \$350 million to a fourth round of the IIF in February's \$1 billion Jobs Plan (BD: Feb 18, Mar 27, 2013).

The Government spokesperson said draft legislation had been released for a quarterly credits system for the 45 percent research and development tax offset from January 1, 2014, delivering enhanced cash flow benefits.

The Budget increased spending on the Pharmaceutical Benefits Scheme by \$143.2 million with \$691 million over five years in new listings under the Scheme, including for chronic nerve pain, hepatitis C and Parkinson's disease.

Medicines Australia welcomed a negotiated "\$2.3 billion downward revision on PBS expenditure [which] can be directly attributed to the agreement between the industry and the Commonwealth".

Medicines Australia media communications manager Jamie Nicholson told Biotech Daily that the negotiated savings came primarily from price disclosure of new generics entering the market putting competitive pressure on existing suppliers as well as mandatory off-patent price cuts.

AUSTRALIAN RESEARCH COUNCIL - WELCOMES EXTRA \$135.3m

Australian Research Council chief executive officer Prof Aidan Byrne said he welcomed last night's Budget announcement of an additional \$135.3 million.

Prof Byrne said the Future Fellowships scheme was due to terminate this year but the Government had provided an additional round which would support 150 researchers.

"This is a great scheme that has worked extremely well and is strongly supported throughout the research sector," Prof Byrne said.

"The ARC has just completed a consultation process with the sector on the Future Fellowships scheme and there is overwhelming acknowledgment that it is meeting its objective of attracting and retaining outstanding mid-career researchers," Prof Byrne said.

"Our Future Fellows are undertaking research critical to our nation, for example, two of our inaugural Future Fellows: Prof Kathy Belov is working to save the Tasmanian Devil from extinction researching the facial tumors that are decimating our native population and with great results; and Professor Mark Kendall developed the Nanopatch for efficient vaccine delivery which won him the 2011 Australian Innovation Challenge," Prof Byrne said.

BIOTECH DAILY – NO PAIN, NO GAIN

There has been a great deal of criticism of the Governments of Kevin Rudd and Julia Gillard, with the initial axing of the Commercial Ready Grant scheme not a great welcome to the innovation sector from the incoming Government.

Following that blow, Ministers Kim Carr and Greg Combet appear to have appreciated that sunrise industries create more jobs than sunset industries, but they are still wedded to subsidizing failing auto-manufacturers and the not-poverty-stricken mining companies.

A bold Budget for Australia would have slashed unproductive industry welfare, upper and middle class welfare, Defence spending and alleged security spending.

Innovation, including biotechnology, clean technology and information and communications technology are the future industries and employers, and deserve a whole-of-industry investment program of the size and controversy of the National Broadband Network, the National Disability Insurance Scheme or the Gonski education reforms, instead of piecemeal crumbs from the Treasurer's table.

Such an investment - just a couple of Collins Class submarines or a new fighter jet program - would provide all the funding commercial biotechnology could ever want, but the case needs to be made to Canberra and through the mainstream media to the general public, which is receptive to Australia leading the way in solar power, fibre optics, Cochlear ear implants and drug discoveries like penicillin, Relenza and Gardasil.

Given that a few billion dollars were never going to be found for innovation, we should be grateful that there were indeed not only no cuts, but assurances of the continuation of existing programs and increased expenditure for the NHMRC and ARC programs.

It is also worth reflecting that - despite the daily calls that 'We'll all be ruined!' - Australia has one of the world's highest living standards and historically – despite a slight increase in the Howard years – one of the lowest total tax-to-GDP ratios in the OECD, which means that Australian Governments have, for decades, provided good value for money.

The Budget was generally positive for biotechnology.

David Langsam
Editor

GBS VENTURE PARTNERS – NO CUTS A VOTE OF CONFIDENCE

GBS managing partner Dr Geoff Brooke told Biotech Daily that in the wake of the global financial crisis, he welcomed the fact that there were no cuts to the Budget affecting biotechnology.

"At a time of a big unexpected budget deficit, the fact that they haven't touched biotechnology is a vote of confidence in our sector," Dr Brooke said.

Dr Brooke said that the Government's decision not to cut any of the promised \$450 million funding for the Innovation Investment Funds over four years was welcome.

[NORTON ROSE - BUDGET WINS FOR THE HEALTH SECTOR](#)

The London-based law firm, Norton Rose, has praised the Federal Budget. Melbourne pharmaceutical and life sciences partner Bernard O'Shea writes:

The 2013 Budget papers suggest that the health sector is going to face significant growth and require significantly increasing expenditure, with several mentions of Australia's ageing population, the increase in demand for healthcare services and increasing cost. One might expect that a significant portion of the expenditure allocated to the National Disability Insurance Scheme will flow into the broader health sector.

The Budget also records a further significant increase in the take-up of private health insurance, suggesting that Australians are concerned both about the cost and availability of quality health services.

The Budget attempts to address stresses in the health sector, including incentives for doctors in rural areas, expansion of the care in the home program and \$660 million over five years for incentives for aged care providers to invest in residential care facilities.

The Budget recognizes the potential ongoing dividends from the price disclosure regime, and allocates \$691 million over five years for the inclusion of new medicines in the PBS, including drugs for chronic nerve pain, chronic hepatitis C and Parkinson's disease.

But the Budget papers also state that "PBS estimates do not include the potential listing of new drugs following recommendations by the Pharmaceutical Benefits Advisory Committee", suggesting that no allowance has been made for drugs not yet recommended for listing by that Committee.

More than \$500 million has also been allocated to a program of Innovation Precincts.

Given the focus of this program on innovation and promoting collaboration between business and research institutions, one might expect that this will create some considerable opportunities - particularly for the biotechnology sector.

Given the obviously fiscally constrained position of the Government, the Budget presents a reasonable combination of settings and programs for both the pharmaceutical and life science sector and the health sector.

For the longer term, the Budget continues to recognize the value of innovation, and the need to support it through education, infrastructure and a range of incentives, such as the R&D concession.

Bernard O'Shea

[MEDICINES AUSTRALIA – MOU MAKES PBS SUSTAINABLE](#)

Medicines Australia chief executive Dr Brendan Shaw said that the Budget recognized that the Government's memorandum of understanding with Medicines Australia "continues to keep the Pharmaceutical Benefits Scheme sustainable".

Dr Shaw said the Budget reflected the Government's commitment to the memorandum, which agreed to no further price-related savings measures for the life of the agreement. "PBS spending growth is currently at historically low levels, so it's clear that the MoU and previous reforms are working and it's clear that the PBS is sustainable," Dr Shaw said.

"The \$2.3 billion downward revision on PBS expenditure can be directly attributed to the agreement between the industry and the Commonwealth," Dr Shaw said.

"It shows that responsible agreements such as the MoU provide a robust framework for managing the PBS," Dr Shaw said.

"They provide material benefits to governments and taxpayers," Dr Shaw said.

"This Budget outcome should also provide the Government with the confidence that it can act expeditiously on [Pharmaceutical Benefits Advisory Committee] recommendations and provide Australian patients with timely access to new medicines," Dr Shaw said.

AUSBIOTECH - FEDERAL BUDGET 2013: NO SURPRISES FOR BIOTECH

Ausbiotech says the Budget “provided no surprises for biotechnology and has instead confirmed the features of the ‘Innovation and Industry Policy - A Plan for Australian Jobs’”. The Policy included \$350 million in venture capital funds for a new round of the Innovation Investment Fund program to stimulate private investment in Australian start-ups, 10 Industry Innovation Precincts worth \$500 million, of which , two have commenced work, and support to implement to the recommendations of the Clinical Trials Action Group. The Federal Budget also confirmed ongoing support for Commercialisation Australia of almost \$75 million per year over the forward estimates.

Ausbiotech said that the new programs were funded by a \$1 billion cut over the forward estimates period for large corporations, that is more than \$20 billion in turnover, under the Research and Development Tax Incentive.

Ausbiotech chief executive officer Dr Anna Lavelle said the research and development tax incentive was delivering “much-needed support to innovative Australian enterprises, and the time has now come for Dr Terry Cutler’s vision of the tax incentive to be realised, with a raising of the turnover cap from \$20 million to \$50 million”.

“Ausbiotech applauds the continuation of the Innovation Investment Fund program, which has been critical to the biotechnology industry, especially in the wake of the [global financial crisis],” Dr Lavelle said.

“Access to capital, and at the right price, is a serious bottleneck to innovation, as Australia has substantially more innovation than capital,” Dr Lavelle said.

Ausbiotech said that the Industry Innovation Precincts would receive more than \$500 million worth of support to set up networks to bring together industry, companies, universities, research institutions and experts in technology and business.

Ausbiotech said that in acknowledgement of the Australian pharmaceutical industry’s positive outlook - exporting about \$4 billion a year, employing more than 40,000 people, and investing more than \$1 billion a year in research and development and the current pressures it faces, the Government said it would boost opportunities for the pharmaceutical industry by expediting the recommendations from the Clinical Trial Action Group Report aimed at advancing Australia’s position as a leader in clinical research and improve our attractiveness as a destination for clinical research investment.

“Ausbiotech applauds the Governments support to action the recommendation of Clinical Trial Action Group, while noting that implementation was well overdue,” Dr Lavelle said.

BIO-MELBOURNE NETWORK – NO SURPRISES

Bio-Melbourne Network chief executive officer Michelle Gallaher said that the Federal Budget was a “no surprises budget”.

“I am relieved to see no cuts to the innovation programs in place,” Ms Gallaher said .

“Another \$350 million round of the [Innovation Investment Fund] is welcomed and changes to venture capital tax arrangements to improve clarity and certainty for investors as well as encouraging participation by angel syndicates is small, but good, news,” Ms Gallaher said.

“The \$378.6 million in new funding to [small and medium-sized enterprises] through the small business advisory service and Enterprise Connect will filter through to some in biotech, though probably only a few,” Ms Gallaher said.

“We will roll the dice competing for an Industry Innovation Precinct, hoping to get a slice of action, giving the sector the opportunity to access the Industry Collaboration Fund,” Ms Gallaher said.

AUSMEDTECH, VICTORIA GOVERNMENT

Victoria's Minister for Technology Gordon Rich-Phillips formally opened Ausbiotech's medical technologies conference with 10 grants of \$100,000 each.

Mr Rich-Phillips said the feasibility studies were part of the Health Market Validation Program, a \$15 million competitive grants program designed to encourage innovation in healthcare.

Mr Rich-Phillips said the companies would investigate whether new technologies could solve healthcare challenges identified by Victorian hospitals and health services and if successful could apply for further grants of up to \$1.5 million each.

"The Health Market Validation Program supports collaboration between the public health sector, researchers and companies," Mr Rich-Phillips said.

Mr Rich-Phillips said it was the first time Ausmedtech was held in Melbourne and spoke of the Victoria's assets for life sciences, including world class research making the State "one of the world's leading centres in biomedical research".

He said that Victoria and Massachusetts had created a "building global bridges program" with \$1 million in funding from Victoria.

"As a government, Massachusetts committed to spending \$1 billion over then the next 10 years," Mr Rich-Phillips said.

"Victoria has already invested \$1.8 billion over the last 15 years," Mr Rich-Phillips said.

Mr Rich-Phillips said that Victoria's life sciences sector had continuity of commitment, policy and investment by both Labor and Coalition Governments in Victoria over the last two decades.

The projects funded today include:

Optotech working with Ambulance Victoria to investigate a safe non-invasive method for early detection and treatment of circulatory shock in critically ill patients;

Bionic Enterprises working with the Peter MacCallum Cancer Centre to investigate a simple and more cost-effective pain alleviation device to address chronic pain;

Perfusion Solutions working with Alfred Health to investigate a new preservation technique for donor organs;

Grey Innovation working with The Royal Victorian Eye and Ear Hospital to investigate a surgical implant to treat glaucoma and improve the outcome of eye surgery;

Procept working with Monash Health to investigate a solution to make cardiac output and oxygen consumption measurement simpler, safer, and less costly;

APS Solutions working with Dental Health Services Victoria to investigate a device that will offer a plaque removal solution for children and people with disabilities;

Grey Innovation working with Eastern Health to further investigate developing a miniature nebuliser for the treatment of chronic respiratory illnesses;

and a second project working with The Royal Women's Hospital to investigate a simple, fast, accurate and low cost nucleic acid detection test for sexually transmitted infections for use by health workers in community health clinics;

Medtech Healthcare working with Peninsula Health to investigate a method of remote monitoring for chronic heart failure patients to automatically report, in real-time, personal health data to clinicians, via the internet or portable smart devices; and

Biota working with Monash Health to investigate a safe anti-viral for the treatment of children under five years of age who present with symptoms of human respiratory syncytial virus.

Mr Rich-Phillips also launched the 'Code of Best Practice for Reporting by Life Science Companies' in collaboration with Ausbiotech and the ASX.

MESOBLAST

Mesoblast says that an intra-coronary infusion of its adult stem cells following an anterior acute myocardial infarction was safe, feasible, and markedly effective in sheep.

Mesoblast said that in the randomized study of 68 sheep, a single intra-coronary infusion of the company's mesenchymal precursor cells decreased infarct size by 40 percent, abrogated left ventricular adverse remodeling, resulted in a marked reduction of left ventricular volumes, increased small and larger blood vessel density by 71 percent for capillaries and 127 percent for arterioles and prevented heart failure.

The company said that the study, co-authored by chief executive Prof Silviu Itescu and entitled 'Intracoronary Infusion of Allogeneic Mesenchymal Precursor Cells Directly Following Experimental Acute Myocardial Infarction Reduces Infarct Size, Abrogates Adverse Remodeling and Improves Cardiac Function' was published in the American Heart Association journal Circulation Research, and an abstract was available at:

<http://circres.ahajournals.org/content/early/2013/05/08/CIRCRESAHA.112.300730>.

Mesoblast said that study was performed at Rotterdam's Erasmus University Medical Center and was led by Prof Eric Duckers.

The company said that the of mesenchymal precursor cells treatment on infarct size and myocardial perfusion resulted in a significant improvement of both global and regional cardiac function.

Mesoblast said that the study results formed the scientific basis for the current allogeneic mesenchymal precursor cell infusion in myocardial infarction trial, the first to evaluate an allogeneic cellular therapy for acute myocardial infarction delivered by intra-coronary infusion.

The company said that the phase IIa/IIb trial was recruiting in Europe, Australia, and New Zealand, with Prof Duckers as the principal investigator.

Mesoblast fell 11 cents or 1.9 percent to \$5.58.

PRIMA BIOMED

Prima says its share plan raised about \$5 million of the hoped for \$15 million and the company would attempt to place the shortfall to sophisticated or professional investors.

Prima said that shareholders would vote at tomorrow's general extraordinary meeting approve, among other things, the issue of up to \$2 million in aggregate worth of shares from the shortfall to directors of the company.

Prima initially said it would offer the shares at 10 cents each but later changed the price to 95% of the 10-day volume weighted average price to the date of issue, then expected to be May 17, 2013 (BD: Apr 2, 9, 2013).

The company also proposed an option rights issue to raise up to \$5.3 million, through the sale of one option, at two cents each, for every four shares held, exercisable at 20 cents each by June 19, 2017.

Prima was up 0.1 cents or 1.2 percent to 8.4 cents with 1.5 million shares traded.

NEUREN PHARMACEUTICALS

Neuren 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 65.5 percent from 2.9 cents on April 30, to 4.8 cents today, March 15, 2013, and noted a significant increase in trading volume.

Neuren closed up 0.4 cents or 9.5 percent at 4.6 cents with 29.1 million shares traded.

ISONEA

Isona 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 climbed from 18.5 cents on May 14, to 23.5 cents, a 27.03 percent increase, today, May 15, 2013, and noted an increase in trading volumes.

Isona told the ASX that chief executive officer Mike Thomas had "delivered a number of investor and shareholder update presentations in Sydney, Melbourne, Perth and Brisbane".

Isona closed unchanged at 25 cents with six million shares traded.

BIONICHE LIFE SCIENCES

Bioniche shareholders have filed a second meeting requisition calling for a spill of the board.

A previous request was rebuffed by the company with claimed that it did not meet legal requirements under Canadian law (BD: Apr 29, May 6, 2013).

Today the "group of concerned shareholders", led by William Wells and Greg Gubitz, said they had filed a second requisition calling for a special meeting of the shareholders of Bioniche.

The group said that the purpose of the requisitioned meeting was to remove from office all of the current directors of Bioniche and to fill the vacancies by electing six named nominees and one additional nominee to be named by Mr Wells as soon as practicable and sufficiently in advance of the meeting to enable shareholders to form a reasoned judgment concerning the election of such nominee.

The group said that the six "highly qualified and experienced nominees" were Mr Wells, Mr Gubitz, J Spencer Lanthier, Serge Gouin, Dr. Rochelle K Seide and Hugo Wahnish. The group provided biographies of the nominees.

The group said that the first request, which did not detail the nominations was "made pursuant to and in full compliance with the requirements of the Canada Business Corporations Act".

The group said that the requisition was improperly rejected by the board which had "resorted to unacceptable stalling tactics".

The group said that the two reasons given by Bioniche for rejecting the initial meeting requisition had been fully addressed with the Bioniche shares owned by Mr Wells now registered in his name and the proposed slate of nominees to serve as directors provided.

The group said that the Bioniche board has a statutory and fiduciary obligation to call a special meeting without further delay to be held as soon as possible to permit the shareholders to have their say.

Bioniche was up 11 cents or 57.9 percent to 30 cents.

MESOBLAST

Mesoblast executive director Prof Silviu Itescu says his 68,244,642 share holding has been diluted from 26.9 percent to 21.6 percent.

Prof Itescu said the dilution was caused by the placement of 26,970,979 shares, which raised \$170 million in March (BD: Mar 14, 2013).

Prof Itescu said he directly held 67,756,838 shares and a further 487,804 shares through Josaka Investments.

IMPEDIMED

Impedimed says former chairman Dr Mel Bridges will retire at the November annual general meeting and Scott Ward will replace Martin Kriewaldt as a director in July 2013. Impedimed said that Dr Bridges would be replaced by a second US-based director in the implementation of its plan "to refresh the board through a carefully considered process of retirement, and appointment of US based directors".

Impedimed chairman Dr Cherrell Hirst thanked Mr Kriewaldt for his seven year contribution to the company.

The company said Mr Ward was formerly with Medtronic's senior vice-president and president of its cardiovascular division, responsible for worldwide operations.

Impedimed said that Mr Ward was currently a director of Surmodics, Creganna-Tactx Medical and Gillette Children's Specialty Healthcare.

Impedimed was up 1.4 cents or 25 percent to seven cents.

ST VINCENT'S INSTITUTE

The St Vincent's Institute says its 'Unleashing Innovation' forum is less than a week away on May 20, 2013.

The St Vincent's Institute said that the forum would be chaired by its patron Prof Gus Nossal and explore what could be done to make Australia a more innovative nation.

The Forum will discuss innovation with CSL research and development director and chief scientist Dr Andrew Cuthbertson, science writer and broadcaster Leigh Dayton and the founder of Robogals, Marita Cheng.

The Forum will be held at The Edge theatre, Federation Square, Cnr Swanston Street and Flinders Street, Melbourne on May 20, 2013 at 12pm (AEST).

To register, email: enquiries@svi.edu.au or telephone St Vincent's Institute reception on +613 9288 2480.