



Biotech Daily

Wednesday May 14, 2014

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was even, down 0.03 percent on Wednesday May 14, 2014 with the S&P ASX 200 down 1.7 points to 5,496.5 points. Fifteen of the Biotech Daily Top 40 stocks were up, 11 fell, 12 traded unchanged and two were untraded.

Anteo was the best, up 3.5 cents or 18.9 percent to 22 cents with 4.9 million shares traded, followed by Analytica up 13.1 percent to 4.3 cents with 8.1 million shares traded and Prima up 11.6 percent to 4.8 cents with 14.8 million shares traded. Impedimed climbed 8.1 percent; Optiscan and Starpharma were up more than six percent; Oncosil was up 4.35 percent; Patrys and Universal Biosensors were up more than three percent; Alchemia and Phosphagenics rose more than two percent; with Benitec and Sirtex up more than one percent.

Admedus led the falls, down one cent or 9.1 percent to 10 cents with 10.4 million shares traded. Antisense lost 7.1 percent; Circadian was down 6.7 percent; Neuren fell 5.1 percent; Biotron and Ellex fell more than four percent; Genetic Technologies and GI Dynamics shed more than two percent; with Medical Developments, Pharmaxis and Tissue Therapies down more than one percent.

FEDERAL BUDGET

The Federal Budget creates a \$20 billion medical research fund, reduces the R&D Tax Incentive, axes the Innovation Investment Fund and Commercialisation Australia, maintains the National Health and Medical Research Council, and reduces funds to both the Australian Research Council and Cooperative Research Centres.

Delivering his first Budget, last night, Treasurer Joe Hockey said: "We will build the biggest medical endowment fund in the world in just six years."

"We are investing all health savings in this Budget into a \$20 billion Medical Research Future Fund," Mr Hockey said.

"Our medical researchers have led the way, from Howard Florey to Sir Gustav Nossal and from Fiona Stanley to Ian Frazer," Mr Hockey said. "Australians have, through research and innovation, saved millions of lives, not just here but around the world."

Mr Hockey said the Medical Research Future Fund would be "in addition to existing levels of funding through the National Health and Medical Research Council".

He said the Fund would "receive all the savings from the introduction of a \$7 Medicare co-contribution, modest changes to the Pharmaceutical Benefits Scheme and other responsible changes in this Health Budget, until the Fund reaches \$20 billion".

A joint statement by Mr Hockey, Finance Minister Mathias Cormann and Health Minister Peter Dutton said the Fund would receive \$1 billion from uncommitted funds in the Health and Hospitals Fund with amounts equivalent to the health savings measures reinvested in the Fund until it reached the target of \$20 billion in 2019-'20.

The statement said that net interest earnings on the Fund's capital would be available for drawdown the following financial year and the capital preserved in perpetuity.

"The MRFF will be managed by the Future Fund Board of Guardians in accordance with an investment mandate issued by the Treasurer and the Minister for Finance," the joint statement said.

The Ministers said the Fund would provide \$276.2 million over three years from July 1, 2015 in net earnings from the Fund "to fund critical medical research in the medium to long term ... [and] provide a sustained funding stream for medical research, with payments from the MRFF expected to reach around \$1.0 billion per year from 2022-'23.

Budget papers said that over four years the Government would reducing research funding for the Commonwealth Scientific and Industrial Research Organisation by \$111.4 million, the Australian Nuclear Science and Technology Organisation by \$27.6 million and the Australian Institute of Marine Science by \$7.8 million.

Budget papers said the Government would provide \$200.0 million over five years, including \$40.0 million in 2018-'19, to improve the treatment of dementia.

The two rates of the Research and Development Tax Incentive will be reduced by 1.5 percent from 45 percent to 43.5 percent and from 40 percent to 38.5 percent.

The Budget said that Cooperative Research Centre funding would be cut by \$80 million over the forward estimates and the 17th selection round would not proceed, but applications from eligible existing CRCs seeking an extension would be considered on merit by July 3, 2014, as would existing CRCs seeking additional funding.

National Health and Medical Research Council funding increases from \$771.2 million in 2013-'14 to \$859.0 million in 2014-'15, falls to \$798.7m million in 2015-'16 rising again to \$813.0 million in 2016-'17 and \$827.7 million in 2017-'18.

Total Australian Research Council funding which was \$890.0 million in 2013-'14, drops to \$881.0 million in 2014-'15, \$800,249 million in 2015-'16, \$764.9 million in 2016-'17 and \$798.4 million in 2017-'18.

The Government said that the Industry Innovation Precincts Programme would close on December 31, 2014.

[Biotech Daily Editorial](#)

The Federal Government will create a \$20 billion medical research fund with more than \$1 billion in the kitty by January 1, 2015.

As Quentin Tarantino's Django said: "What is there not to like?"

Biotech Daily has been campaigning for a \$2 billion biotech fund for some time and has held discussions with a range of people on how to construct such a fund and take the proposal to Government. There have been expressions of interest for the fund from individuals in the Coalition Government, Labor Opposition and the Australian Greens.

But to be wrong-footed 10-fold by last night's Budget is ... er ... delightful.

The message sent to both the Australian community and the wider world is that the Federal Government is as serious about investing in sunrise industries as it is in not wasting funds on sunset industries.

The size of the Fund stamps medical research as central to this country's future, but does not address how to commercialize that research (see further editorials below).

There are three questions that the Budget papers don't answer. How will the fund grow from the \$1 billion in 2015 to \$20 billion by 2020, how will funds be allocated and how will the discoveries be commercialized?

A joint statement by Treasurer Joe Hockey, Finance Minister Mathias Cormann and Health Minister Peter Dutton said: "The Medical Research Future Fund will be invested and managed by the Future Fund Board of Guardians, which has a proven track record in managing investment portfolios on behalf of the Government and maximizing returns over the long term".

Chaired by former Liberal Treasurer Peter Costello, the board has great experience in finance and investment, but no member appears to have any expertise in medical research or biotechnology. The board may require rapid renewal if it is to invest the funds effectively. Dr Brian McNamee, John Brumby and Peter Beattie leap to mind.

The only true negative is the source of the funding. Relying, in part, on a dramatic change to Australia's Medicare, widely regarded as one of the best, if not the best, national health services in the world, means that recipients of Fund grants will be spending money from co-payments to general practitioners, as well as increased prescription charges. Some members of our society will be able to afford the new charges easily, but others will not. It is a shame that such a positive move as this Fund should be tarnished by the inequality underpinning it.

Never-the-less, Biotech Daily unequivocally welcomes the new Fund, which makes the original \$2 billion commercialization fund idea even more necessary.

David Langsam
Editor

[Walter and Eliza Hall Institute of Medical Research](#)

The director of the Walter and Eliza Hall Institute Prof Doug Hilton says the Medical Research Future Fund will “secure a healthier future for Australians”.

WEHI said that Prof Hilton initiated the 2011 Discoveries Need Dollars campaign that saw thousands of Australians rally on the streets in support of medical research and the government’s investment “aligned with the importance the Australian community placed on health and medical research”.

“Australian health and medical researchers have made discoveries that have improved the lives of million of people in Australia and around the world,” Dr Hilton said.

“This investment from the government is game changing,” Dr Hilton said.

“As a sector we take very seriously the responsibility to spend every cent as wisely and efficiently as we can,” Dr Hilton said.

Dr Hilton said dividends from the fund, expected to be the largest of its type in the world, would be spent exclusively on medical research with payments starting at \$19.9 million in 2015-‘16, rising to \$179.3 million in 2017-‘18 and, by 2023-24, the fund is expected to provide an additional \$1 billion a year for medical research, doubling the government’s investment in medical research within a decade.

Prof Hilton said although there was not yet detail on how the funds would be spent, the first priority should be ensuring the research granting system was highly efficient.

“We need the processes that exist around the administration of research grants to be commensurate with a fund of the size forecast for the Medical Research Future Fund,” Prof Hilton said.

WEHI said that other priorities included supporting the indirect costs of medical research such as electricity and information technology systems, developing a sustainable career structure for early and mid-career researchers and supporting research aimed at making the health system more efficient and productive.

“It is a fabulous time to be a medical researcher,” Prof Hilton said.

“The government has recognized the capacity of Australian researchers to innovate and deliver benefits for the Australian community,” Prof Hilton said.

“This sends a fabulous signal to young researchers that, from the point of view of health and medical research, Australia is open for business,” Prof Hilton said.

“If you are bright and smart and want to make a difference, medical research is a career to consider,” Prof Hilton said.

[Norton Rose Fulbright](#)

Law firm Norton Rose Fulbright Melbourne partner Bernard O'Shea welcomes the Fund but questions the absence of detail on commercialization funding.

Mr O'Shea said the fund would result in a "significant boost to the level of research funding for the academic sector with an expected consequence of new technologies to be commercialized".

"The other side of the ledger will be of great interest to the sector," Mr O'Shea said. "This will largely be dictated by the mandate given to the Future Fund as to how the [fund] is to be invested."

"It would be a very significant departure from existing investments under the control of the Future Fund to see these dollars coming back into local entities seeking to commercialize health-related technologies," Mr O'Shea said.

Mr O'Shea said that the fund had the potential for both increased NHMRC funding as well as greater certainty of funding in the short term, but "there must be some concern that this is regarded as a complete solution to research funding in this sector".

"This might not be as attractive in the medium to longer term - even if this is premised on the existing level of NHMRC funding remaining intact, noting that the budget states that the MRFF monies are in addition to existing funding," Mr O'Shea said.

"Perhaps the best news for the commercial sector is that the R&D concession appears to have been left intact, apart from what appear to be minor adjustments to reflect the reduced company tax rates," Mr O'Shea said. "This however is counter-balanced by the cessation of Commercialisation Australia and the Innovation Investment Fund."

Mr O'Shea said that there was no specific mention in the Budget to address the commercialization gap for those looking to commercialize emerging research, as well as nothing to suggest that research which was translated into practice would be rewarded.

"The avowed intent of the MRFF is to fund research directed to delivering improved health and medical outcomes for all Australians", Mr O'Shea said. "It will be interesting to see how this manifests itself in practice."

[Bio-Melbourne Network](#)

Bio-Melbourne Network chief executive officer Michelle Gallaher says the Fund "is great for science but offers no advantage whatsoever for biotech development".

"All of the commercialization programs have been axed ... [with] valuable industry engagement platforms such as the Cooperative Research Centres and CSIRO losing a huge proportion of funding support," Ms Gallager said.

Ms Gallaher said Australia was "set to become the medical research supermarket of the world" with companies moving offshore for funding and commercialization.

[Australian Private Equity & Venture Capital Association](#)

The Australian Private Equity & Venture Capital Association says the Federal Budget has abolished “key innovation industry programs”.

Avcal chief executive Yasser El-Ansary said that “everyone was expecting to see plenty of short-term pain for businesses in this budget - and that’s exactly what we got”.

“But what we were also expecting to see ... was a plan which set out the longer-term vision for what the Australian economy will look like in the next five or 10 years,” Mr El-Ansary said.

Avcal said that the Budget abolished key programs, “including the highly successful 15-year old Innovation Investment Fund, as well as cuts to the research and development tax system” and Mr El-Ansary said that abolishing the Innovation Investment Fund was “a major set-back to Australia’s capacity to foster a stronger venture capital industry”.

Mr El-Ansary said that the Fund could support greater investment in biotechnology, but it had to encompass a focus on commercialization as well as pure research.

[Medicines Australia](#)

Medicines Australia chief executive officer Dr Brendan Shaw said the Federal Government had honored the investment in the PBS and it was “pleasing that savings generated in the health portfolio will go back into medical research”.

“The new Medical Research Future Fund will be a positive step forward and we are keen to work with the Government to make this research fund a reality,” Dr Shaw said. “A medical research fund in Australia will create an environment in public and private research which can deliver the results that Australian patients deserve.”

Dr Shaw said that patient co-payments “may result in patients not filling their scripts and that skipping medicines can lead to adverse patient outcomes and more costly medical interventions, including hospital admissions, in future,” Dr Shaw said.

[Cooperative Research Centre Association](#)

Cooperative Research Centre Association chairman Tony Staley said that “every time we have been reviewed in the past, we have shown that cooperative, large scale collaboration with the end-users in the driver's seat is effective”

The CRC Association said the Budget included a cut to the CRC program of \$80 million over the forward estimates and the current round would not proceed.

The Association said the Government wanted to see effective applied research working closely with industry and “no one is better positioned to deliver that than the CRCs”.

REGENEUS

Regeneus says a study has shown that “autologous administration of stem cells for neuropathic trigeminal pain significantly reduced pain intensity at six months”.

Regeneus said the study, entitled ‘A preliminary report on stem cell therapy for neuropathic pain in humans’ was co-authored by clinical development director Dr Richard Lilischkis and was published in the Journal of Pain Research.

An abstract is at: http://www.dovepress.com/articles.php?article_id=16748.

Regeneus said the paper described the safety and early efficacy data for the use of its Hiqcell fat-derived stem cell therapy for neuropathic pain sufferers with persistent, severe and intolerable pain in the face and dental region.

Regeneus said the investigation of Hiqcell on pain in the trigeminal cranial nerve, or the oral and facial region, was conducted by pain management specialist and maxillo-facial surgeon Dr Russell Vickers and plastic and reconstructive surgeon Dr John Flood.

The paper concluded: “This preliminary open-labeled study showed autologous administration of stem cells for neuropathic trigeminal pain significantly reduced pain intensity at six months and is a safe and well tolerated intervention.”

Dr Vickers said that managing chronic pain often required a multidisciplinary approach and current pharmaceutical medication could cause adverse side effects.

“In the study group, in addition to a significant reduction in pain, there were improvements in headache, cosmetic facial deficits and myelinated nerves,” Dr Vickers said.

Regeneus was up two cents or 5.3 percent to 40 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says it has raised \$7.2 million in a placement at \$1.658 a share Asian and European institutional and professional investors.

Clinuvel said that its directors subscribed for \$300,000 “at terms equivalent to those subscribed by all other participants to the placement” and subject to shareholder approval.

The company said \$1.658 was a 5.0 percent premium to the 20-day volume weighted average price to May 8 and a 10.5 percent premium to the May 9, 2014 closing price.

Clinuvel said the funds were for Scenesse for vitiligo and further product development.

Clinuvel was unchanged at \$1.50.

PSIVIDA

Psivida says it plans to seek US approval for Medidur for posterior uveitis, based on data from one phase III trial.

Psivida said that Medidur used the same injectable sustained release micro-insert delivering the same dose of the same drug as Iluvien for chronic diabetic macular oedema and the company would be able to reference the Iluvien new drug application, including data from Iluvien clinical trials in a Medidur new drug application (BD: Jul 20, 2012).

The company said that posterior uveitis was an inflammatory disease of the eye, affecting about 175,000 people in the US and was the third largest cause of blindness.

Psivida chief executive officer Dr Paul Ashton said the revised regulatory strategy for Medidur had “the potential to significantly accelerate US commercial availability and reduce overall development costs”.

“We remain optimistic that the FDA will approve Iluvien, which we believe will permit us to seek US approval with data from a single phase III trial for Medidur along with clinical data about our proprietary inserter,” Dr Ashton said.

Psivida was untraded at \$3.70.

CALZADA

Calzada says Max Johnston and Philip Powell have been appointed as non-executive directors with immediate effect.

Calzada said that Mr Johnston was formerly the president and chief executive officer of Johnson & Johnson Pacific and the director of Johnson & Johnson Research.

The company said that prior to joining Johnson & Johnson, Mr Johnston held senior roles with Diageo and Unilever in Europe and he was currently a director of Medical Developments, Enero Group and Probiotec.

Calzada said Mr Powell had more than 15 years experience in investment banking specializing in capital raisings, initial public offers and mergers and acquisitions, with 10 years in senior roles at OAMPS and 10 years with Arthur Andersen.

Calzada fell half a cent or 4.8 percent to 10 cents.

PROGEN PHARMACEUTICALS

Progen says non-executive chairman Jitto Arulampalam replace acting managing director Heng Tang who has been appointed subsidiary Pharmasynth's managing director.

Progen said the company would relocate to Melbourne, with Pharmasynth continuing at Darra, Queensland.

The company said that the relocation of the corporate office would provide a platform for more focused engagement with shareholders and corporate partners, as well as assist in attracting employees.

Progen said that appointing Mr Tang as Pharmasynth managing director brought "strong management and financial experience to the manufacturing arm of Progen".

The company said it would begin a formal recruitment process for a new chief executive officer.

Progen was up 8.5 cents or 9.0 percent to \$1.025.