



Biotech Daily

Thursday May 16, 2019

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was up 0.69 percent on Thursday May 16, 2019, with the ASX200 up 43.6 points to 6,327.8 points.

Sixteen of the Biotech Daily Top 40 stocks were up, six fell, 15 traded unchanged and three were untraded. All three Big Caps were up.

Avita was the best, up five cents or 11.4 percent to 49 cents with 21.2 million shares traded.

Actinogen and Telix climbed more than seven percent; Clinuvel was up 5.1 percent; Compumedics, Cynata, LBT and Osprey improved more than four percent; Opthea was up 3.6 percent; Alterity (Prana) and Polynovo rose more than two percent; CSL, Kazia, Neuren and Volpara were up more than one percent; with Cochlear, Cyclopharm, Pro Medicus and Resmed up by less than one percent.

Oncosil led the falls, down half a cent or 7.35 percent to 6.3 cents, with 1.3 million shares traded.

Impedimed, Medical Developments and Nanosonics shed two percent or more; Antisense was down 1.85 percent; with Genetic Signatures down by 0.5 percent.

FEDERAL ELECTION 2019: POLICIES & COMMENT

As we approach this most important election, how do we judge political parties - on their promises, their track record or both?

As far as track records go, the Liberal-National Party has been tearing itself apart in not accepting the science of Climate Change while the Australian Labor Party accepts the science but won't return to a price on carbon, as advocated by the Greens.

In our specific industry, the Greens and Gillard Labor Government delivered the uncapped 45% Research and Development Tax Incentive after much hard lobbying from the industry - led by Ausbiotech under chief executive officer Dr Anna Lavelle.

The previous Senator Kim Carr Commercialisation Australia substitute for the Commercial Ready scheme was too little, too late, and with too many conflicts of interest. The paltry \$80 million-a-year compared to Israel's Office of Chief Scientist's \$US350 million-a-year for a population one-third the size of Australia, said enough.

But Senator Carr has been the Minister or Shadow Minister for Innovation since December 2006. He is passionate about sunrise industries. We would have been more impressed had his bail-outs of the infernal combustion engine industry been conditional on producing Australian second-generation, electric, long-haul semi-trailers and cars.

On the other side of the aisle, then Opposition Leader Tony Abbott, through the member for Higgins, Kelly O'Dwyer, promised there would be no cuts to the R&D Tax Incentive and no cuts to NHMRC and ARC funding. Mr Abbott also promised "No cuts to the ABC, SBS, health or education" immediately before the 2013 election. All were cut. In discussing OECD data on tax rates, one of Ms O'Dwyer's assistants asked: "You don't believe the OECD, do you?" Well, yes, actually, this writer does, along with large, randomized, controlled trials, or 'science'.

And what are the measurable outcomes of the Liberal-National Party Government?

Biotech Daily first believed that the \$20 billion Medical Research Future Fund was a thought-bubble, but it has materialized and is half-way funded. Funds are being dispersed and Biotech Daily has reported on many projects announced by long-term Health Minister Greg Hunt, who appears to have a real passion for his portfolio.

Biotech Daily met Mr Hunt with then Victoria Labor Health Minister Jill Hennessy at the Walter and Eliza Hall Institute launch of Venetoclax for cancer. He has been a good Health Minister, despite his intemperate comments on the Victoria judicial system and supporting Peter Dutton's destabilization of the Liberal leadership.

But we have had six innovation ministers under the Abbott-Turnbull governments and since the rise of Scott Morrison there has been no Innovation Minister.

The Prime Minister for Innovation, Malcolm Turnbull, oversaw the first cut to the R&D Tax Incentive and instead of establishing an Independent Innovation Board to vet the ports, tried to cap the incentive at \$2 million a year and then backed down to \$4 million a year. Some companies making the biggest claims are on the cusp of success (or failure).

THE PROMISES

The Greens are promising a 4% of GDP spend on science and research by 2030, the ALP is promising 3%, also by 2030. It is currently 1.8% of GDP and the LNP has no commitment. All three parties have promised a Science Minister in Cabinet.

[LIBERAL NATIONAL PARTY COALITION](#)

The Liberal Party website's policies do not include any reference to innovation or science, with the policies on research limited to support for its \$20 billion MRFF.

A spokesman for the Minister for Industry Science and Technology Karen Andrews told Biotech Daily that "the Coalition has introduced reforms to encourage companies to do additional R&D, while addressing real concerns about rigging and integrity" and clinical trials were exempt from the proposed \$4 million cap.

Biotech Daily asked whether the Coalition would continue funding the CSIRO, ARC and NHMRC at current levels adjusted for inflation and desist from interference in grants.

The spokesman said the Morrison Government was "committed to ensuring that the CSIRO continues to be a world-leading scientific institution" and said the Coalition invested \$97 million more in CSIRO than Labor did when it was in government and the 2019-'20 CSIRO allocation was in-line with indexation.

The Coalition said it was committed to the National Interest Test (NIT) and only "those applications that meet the NIT definition and score highly in the competitive grants process will be recommended to the Minister for funding".

"This approach creates no additional burden to researchers in preparing their applications but requires them to specifically address the NIT definition."

The Liberal Party spokesman said that it was the Coalition Government that proposed the \$1.1 billion National Innovation and Science Agenda, established Innovation and Science Australia for independent advice to Government and was "the only party to invest in Women in STEM".

According to the Budget papers the long-term allocations to the CSIRO, NHMRC and ARC have not kept up with, and are not expected to keep up with, inflation.

[AUSTRALIAN LABOR PARTY](#)

A spokesperson for Senator Carr told Biotech Daily that Labor's intention was "to support the development of a 21st Century industry structure for Australia that provides quality jobs and underpins prosperity and living standards ... [and] lift Australia's research and development expenditure to 3.0 percent of gross domestic product (GDP) by 2030".

Labor said it would reform the Research and Development Tax Incentive (RDTI) "to help more firms do quality research and development here in Australia and employ more Australians ... [and] firms that collaborate with researchers in universities and public research agencies to create new knowledge will be eligible for a 10 percent premium" on top of the RDTI.

The ALP said it would "change the program objectives of the R&D Tax Incentive" by improving collaboration and "look at the RDTI in a manner in which we can secure savings".

Asked directly if Labor would retain the reduced rate of 43.5 percent capped at \$4 million or return to an uncapped 45 percent, Biotech Daily was referred to the ambiguous policy.

The ALP said it would conduct "a root-and-branch inquiry into strengthening our research capabilities across the whole of government ... [and] restore the integrity of the Australian Research Council, by ending political interference in the grants process".

THE GREENS

The Greens pledged to meet a 4.0 percent of GDP science, research and innovation target by 2030, make jobs for scientists and researchers more secure and reverse funding cuts to CSIRO and other public research agencies.

The Greens' Research and Development Policy says it supports "a strong research sector in Australia to help move away from the polluting industries of the past and deliver the jobs of the future".

The Greens promised to create a 'Protecting Science' package, consisting of a \$2.6 billion boost to the ARC, NHMRC and Cooperative Research Centres over 10 years; provide \$1.05 billion through the Medical Research Future Fund; fund four new integrated health research centres; increase funding to the Research Infrastructure Investment Strategy by \$2.2 billion over 10 years; restore the Sustainable Research Excellence program and boost university research; provide \$60.2 million for international collaboration; and provide \$185.1 million to ensure Open Access Publishing of Government-funded research.

The Greens said they would spend more than \$2.5 billion over the decade to support equitable and ongoing employment opportunities for researchers; provide support for women in science; allocate funding to support early and midcareer researchers; and invest in teacher training in STEM education.

The Greens said they were committed to an additional \$40 million in annual funding to the CSIRO, reversing the Coalition's Budget cuts, as well as funding the Australian Nuclear Science and Technology Organisation, the Australian Institute of Medical Scientists and providing more than \$100 million to the Department of Industry, Innovation and Science.

The Greens said they would improve the R&D Tax Incentive by reversing Government cuts and providing a 20 percent non-refundable tax offset for companies that hire science technology engineering and mathematics (STEM) doctoral students.

THE RESPONSE

SCIENCE AND TECHNOLOGY AUSTRALIA

Science and Technology Australia provides a comparison of the major parties policies on its website: <https://scienceandtechnologyaustralia.org.au/policy-and-advocacy/>.

Science and Technology Australia president Prof Emma Johnston said that "despite strong support from Australians, we are facing downward trends in government investment in science and technology, no visionary national plan, and increasing job insecurity in our sector".

ASSOCIATION OF AUSTRALIAN MEDICAL RESEARCH INSTITUTES

In a media release, the Association of Australian Medical Research Institutes (AAMRI) said it was "delighted to receive confirmation ... from the Australian Labor Party that a future Labor Government would provide the strong support needed to build a world class health and medical research sector".

AAMRI said that Labor had agreed to use the MRFF and work with the sector to invest in mid-career researchers and women in science technology engineering and mathematics. AAMRI said the \$125 million for cancer research as part of Labor's Medicare Cancer Plan was "strongly welcomed by the sector and will help our researchers to find new cures and treatments, giving new hope to patients and their families".

MEDICINES AUSTRALIA

Medicines Australia welcomed the Labor Party announcement to reform the Research and Development (R&D) Tax Incentive if elected on May 18, 2019.

Medicines Australia said it welcomed the appointment of former chief scientist Prof Ian Chubb as leader of the ALP's proposed review of Australia's research sector.

AUSBIOTECH

A joint statement by Ausbiotech, Medicines Australia, MTAA, Biomedical Research Victoria, the Bio-Melbourne Network and Research Australia, called on the contenders to "preserve the R&D Tax Incentive", meaning to leave it at 43.5 percent with no cap.

BIOTECH DAILY

Biotech Daily is concerned that the Liberal National Party is divided on science. The canary in the coal mine, so to speak, is the coal mine. If the LNP doesn't understand Global Warming, science and innovation are off to a bad start.

Ministerial interference with research grants is more Stalinist than utilitarian, and the first refusals were misplaced. How does one prove the "national interest" in basic research on a molecule that may or may not have efficacy for cancer or a diagnostic that may or may not be commercializable, let alone test ice-cores for carbon dioxide concentrations?

The cuts to funding under Prime Minister Turnbull do not bode well for a Government in which innovation has disappeared without trace, but the commitment to the MRFF and the passion of Health Minister Greg Hunt are the Government's saving graces.

The ALP lacks imagination on innovation and commercialization. Despite promises of meetings with Opposition Leader (and local Member of the House of Representatives), Bill Shorten, the meetings never materialized.

But the RDTI is excellent for commercialization and Senator Carr has an institutional memory of the operations of his portfolios. The RDTI needs to be reviewed by an Independent Innovation Board, rather than the blunt instrument of cuts and caps.

The Greens may well hold the balance of power in the next Parliament and their policies are the most innovation-friendly.

The Member for Melbourne, Adam Bandt, knows his constituency includes CSL, the Parkville Precinct and scores of biotech companies. Greens leader, Senator Richard di Natale, is a medical doctor. The State member for Melbourne, Ellen Sandell, is a former CSIRO research scientist.

Whichever major party forms Government, it would be good for innovation and biotechnology for the Greens to have influence, if not the balance of power.

The Labor Party has demonstrated a greater commitment to innovation and commercialization than the Coalition, while the Coalition has demonstrated a greater commitment to medical research.

Finally, the Coalition has sought re-election on the platform that it is a better manager of the economy. This is contestable in that taxation as a percentage of GDP – if you believe OECD data – has been lower under Labor than the Coalition. A report in the Fairfax papers last weekend said GDP growth for the past six years of LNP Government was 2.6 percent, identical to that of the previous Labor Government. What the article omitted was that Labor's 2.6 percent growth included the Global Financial Crisis and the LNP 2.6 percent was during a world-wide growth period.

Every vote counts. And that is a fact.

David Langsam, Editor

[VITTAIL, PETER MACCALLUM CANCER CENTRE,
COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION](#)

Vittail says it hopes to raise \$6 million to work with the Peter MacCallum Cancer Centre and the CSIRO to identify a molecule to block the E6AP protein for cancer.

In a media release, the CSIRO said Vittail co-founder and the Peter MacCallum Cancer Centre's Prof Ygal Haupt found that blocking the E6AP protein could improve the body's defences against certain cancers such as prostate cancer and human papillomavirus (HPV) related cancers.

Vittail said HPV cancers produced an E6 protein that interacted with E6AP and caused it to clear the tumor suppressor protein, p53.

The company said Prof Haupt found that cancers not caused by HPV over-expressed the E6AP protein and degraded tumor suppressors such as PML and p27.

Vittail executive director Dr John Deadman told Biotech Daily that the company hoped to raise \$6 million to fund the work over three years.

Vittail said the funds would progress the company's projects to "a stage where the company can licence its intellectual property" and the licensee would need to conduct studies required for an investigational new drug application to the US Food and Drug Administration.

He said that Vittail, the Peter MacCallum Cancer Centre and the CSIRO would screen for molecules to block the E6AP protein which was dysregulated in the oro-genital HPV cancers and overexpressed in prostate cancers.

Dr Deadman said that the funding round was being conducted by the TSL Group whose principal was Acrux chairman Ross Dobinson.

Mr Dobinson told Biotech Daily that the funding round hoped to raise \$6 million at \$1.00 a share with a \$50,000 minimum.

Mr Dobinson said that pending confidential agreements the CSIRO would hold 10 percent of Vittail and a company presentation said it would have an indicative capitalization of \$7.6 million with 6.54 million preference shares and 1.02 million ordinary shares.

The presentation said that Vittail's founders were the CSIRO's Dr Tom Peat, Prof Haupt and Dr Deadman, with Prof Haupt and Dr Deadman on the management team, and Mr Dobinson and former GBS Venture Partners principal Dr Geoff Brooke as directors.

Vittail said it found that it could clear cancers in animal models by removing E6AP through genetic knock-down or ribonucleic acid interference (RNAi).

Prof Haupt said that HPV was "a major cause of cancers of the inner surfaces of the body and irrespective of where these cancers occur, they share the E6AP protein as a common driver".

"We've developed a way to block this cancer-promoting protein and we expect this approach could be effective in developing treatments for HPV-related cancers plus some non-HPV-related cancers, in particular prostate cancer, which also rely on E6AP as a driver," Prof Haupt said.

"Now we'll use our experience and capabilities in drug discovery to help Peter Mac and Vittail turn that research into a commercial reality," Prof Haupt said.

Vittail said that previous funding was used for 18 months of research to set up the techniques required for a fragment-based, drug design strategy, such as an alpha screen assay and cell line assays.

The company said the three-year drug discovery project would develop personalized and stratified medicine for either HPV infection or raised E6AP protein levels.

For further information about the capital raising contact Mr Dobinson by email at:

ross@tslgroup.com.au.

Vittail is a public unlisted company.

BIONOMICS

Bionomics says further data analysis of its phase II BNC210 for post-traumatic stress disorder trial shows that a different dose might be appropriate.

Last year, Bionomics said its 193-patient phase II BNC210 trial failed to meet its primary endpoint for post-traumatic stress disorder (PTSD) (BD: Oct 2, 2018).

Today, the company said pharmacometric (PK) modelling showed that exposure to its BNC210 liquid suspension formulation was “insufficient to achieve efficacy”.

The company said exposure-response modelling indicated the potential for BNC210 for PTSD symptoms but required adequate blood levels of 25 milligrams mg.hr/L.

Bionomics said the findings would justify further evaluations of BNC210 for PTSD for future trial design to demonstrate efficacy.

The company said it had encouraging data on the improved solid dose formulation of BNC210, which was intended for use in future trials.

Bionomics said it would present the expanded data at the Society of Biological Psychiatry’s meeting in Chicago, Illinois from May 16 to 18, 2019.

Bionomics fell half a cent or 3.85 percent to 12.5 cents.

NUHEARA

Nuheara says its Iqstream TV has achieved all necessary certifications and is now available through its website, or from specialist retailers from June 10, 2019.

Nuheara said users would be able to balance television volume independently from other listeners, ambient sounds and conversations, designed for use with its Iqbuds Boost.

The company said it would include an extension to its applications for users to control.

Nuheara said the Iqstream TV would retail at \$139.00.

Nuheara fell 0.2 cents or 2.5 percent to 7.9 cents with 4.5 million shares traded.

PRESCIENT THERAPEUTICS

Prescient says it has been allowed a Canadian patent for PTX-200 for the treatment of cancer.

Prescient said the patent, titled ‘Anticancer combination therapy including triciribine’ would provide intellectual property protection until 2028.

The company said that the claims in the patent covered “compositions of PTX-200 with taxanes and platinum compounds for the treatment of patients with cancer”.

Prescient said the patent bolstered its patent estate for PTX-200 with patents for use already granted in key jurisdictions.

Prescient was unchanged at 4.3 cents with 4.8 million shares traded.

G MEDICAL INNOVATIONS HOLDINGS

G Medical said it has US provider participation agreements with Prime Health Services and Ancillary Care Services for its mobile telephone vital signs sensors.

The Company said that its wholly owned subsidiary G Medical Diagnostic Services had executed the agreements with the Ontario, California-based Prime Health Services and Irving, Texas-based Ancillary Care Services for the vital sign sensor technology.

In a separate announcement at 3.58pm, G Medical said a newspaper article claiming its Patch had US Food and Drug Administration approval was incorrect and the company had applied for FDA approval for the patch.

G Medical fell one cent or 4.2 percent to 23 cents with 1.6 million shares traded.

BOTANIX PHARMACEUTICALS

Botanix has told the ASX that it has retracted the claim that its marijuana-derived drug BTX1801 for skin infections was “bacterial resistant”.

Botanix said that in its presentation to the Cannacord Genuity Cannabis Conference in New York it said that “BTX1801 may have the following benefits ... [including] bacteria do not form resistance to BTX1801”.

Today the company said that “as investigations are still under way, Botanix does not consider, at this stage, that it has a reasonable basis for this statement and retracts it”.

Earlier today, Botanix requested a trading halt to “make an announcement to a query raised from ASX”.

Botanix was up half a cent or 4.8 percent to 11 cents.

CANN GLOBAL (FORMERLY QUEENSLAND BAUXITE)

Cann Global says it has in-principle relisting approval from the ASX and must meet admission requirements in chapters one and two of the Listing Rules.

Cann Global said it would call an extraordinary general meeting, required for the relisting process, in the coming days.

The company said it would appoint John Easterling, Jonathan Cohen and David Austin to the board, with director Meyer Gutnick not seeking re-election.

Cann Global said executive chair Pnina Feldman and managing director Sholom Feldman would continue on the board.

The company said it would appoint Alex Neuling as company secretary on relisting.

Cann Global said Mr Neuling was previously the founder and principle of Erasmus Consulting, an audit manager for Deloitte in Perth and London, and had over 20 years' experience at Apollo Consolidated, Lepidico, Northern Iron, Aurora Oil and Gas, and Eureka Energy.

The company said its subsidiary marijuana companies would have separate management teams, responsible to the board.

Cann Global said the ASX would require it to make disclosures in regard to orders made by the Court because of its executive directors' involvement in the Legend proceedings, currently subject to appeal.

Cann Global was in a suspension at 3.7 cents.

CSL

CSL says it has appointed Dr Paul McKenzie as its chief operating officer, effective from June 3, 2019.

CSL said Dr McKenzie would lead its newly formed end-to-end supply chain organisation and strategy.

CSL said Dr McKenzie previously held leadership roles at Johnson & Johnson, Bristol-Myers Squibb, Merck and most recently as Biogen's executive vice president of pharmaceutical operations and technology.

The company said Dr McKenzie held a Bachelor of Science from the Philadelphia, -based University of Pennsylvania and a Doctor of Philosophy from the Pittsburgh, Pennsylvania-based Carnegie Mellon University.

CSL was up \$2.14 or 1.1 percent to \$202.98 with 730,484 shares traded.