



Biotech Daily

Thursday November 22, 2018

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market recovered 0.86 percent on Thursday November 22, 2018 with the ASX200 up 48.5 points to 5,642.8 points. Nineteen of the Biotech Daily Top 40 stocks were up, 10 fell, six traded unchanged and five were untraded. All three Big Caps rose.

Imugene and Impedimed were equal best, up 9.1 percent to 2.4 cents and 30 cents, respectively, with 48.0 million shares and 334,611 shares traded, respectively. Clinuvel climbed 8.7 percent; Oncosil was up 5.9 percent; Orthocell, Paradigm and Universal Biosensors improved more than four percent; CSL and Nanosonics were up more than three percent; Airxpanders, Cochlear, Compumedics, Cyclopharm and Immutep rose more than two percent; Avita, Cynata, Mesoblast, Opthea and Volpara were up more than one percent; with Polynovo, Resmed and Starpharma up by less than one percent.

Factor led the falls, down 0.1 cents or 33.3 percent to 0.2 cents with 81.7 million shares traded. Benitec fell 4.8 percent; Neuren and Osprey were down three percent or more; Ellex, Prana and Prescient shed more than two percent; Medical Developments was down 1.1 percent; with Pro Medicus and Telix down by less than one percent.

[BIOTECH DAILY VICTORIA ELECTION 2018 EDITORIAL](#)

The four years of Baillieu-Napthine Liberal Government and four years of Andrews Labor Government have been an effective control-versus-active clinical trial of biotech policy.

And we use the terms advisedly.

The Bracks and Brumby Victoria Labor Governments, like the Beattie and Bligh Queensland Labor Governments, were excellent for biotechnology, and perhaps less-so for the other sunrise industries of clean-tech and information technology.

The industry consensus is that we are grateful that the 2010-2014 Baillieu-Napthine Liberal Government did not cut the previous Government's spending on our sector.

Just before the 2014 election we were swamped with media releases from the Liberal Party promising that if re-elected, it would fund projects that should have been funded in the previous four years.

Last week, Biotech Daily received its first and only media release from Liberal Shadow Innovation Minister David Southwick, promising a \$32 million 'Innovation Package' to establish six industry commercialization institutes, a \$9 million voucher program, a new office of Chief Innovation Officer, internships and a \$1 million small business grants scheme.

Biotech Daily recalls clearly the 2015 Federal Liberal Prime Minister Malcolm Turnbull's promise to put innovation at the centre of his government. Since then we have had five Innovation Ministers and currently have neither an Innovation nor a Science Minister.

While Federal matters are not necessarily State matters, it doesn't build confidence.

Worse, the Abbott-Turnbull-Morrison Governments have cut funding to our sector – first with the penny-pinching 1.5 percent reduction to the Research and Development Tax Incentive and now the proposed \$4 million Tax Incentive cap for companies on the verge of success (or failure).

At a State level, the Liberal Party has been lacklustre and the current policy appears to be more focused on the benefits of decentralization to the regions than it is on sunrise industries. It isn't very innovative.

The Andrews Labor Government, through Health Minister Jill Hennessy and Innovation Minister Philip Dalidakis has continued the work started by Premier Steve Bracks and then Treasurer and Innovation Minister, and later Premier, John Brumby.

Apart from "big ticket" items such as \$543 million for the Victoria Heart Hospital at Monash and support for the Johnson & Johnson Monash Innovation Partnering Office, there have been scores of announcements of funds for research, industry conferences, overseas offices and trade deals.

It's not on the scale of the Bracks-Brumby Governments, but it adds up to tens of millions of dollars a year.

The support to the sector and companies from the State Government's Department of Economic Development, Jobs, Transport and Resources is immeasurable.

Then there are investments in industry programs, the Victorian Clinical Trials Gateway with St Vincent's Hospital, Biocurate combining the University of Melbourne with Monash University, \$20 million for innovative research, mental health programs, the proton beam project, the Aikenhead Centre for Medical Discovery, and support for the Murdoch Children's Research Institute at the about-to-be extended Royal Children's Hospital.

Or as Prof John Cleese said so eloquently: "What has Labor ever done for Biotech?"

In 2014, the Greens were upfront and said they did not have a State biotechnology policy.

This year is different. Geneticist and former CSIRO staffer Ellen Sandell is the Legislative Assembly Member (MLA) for Melbourne, which - like its Federal equivalent - is home to a large number of biotechnology companies and their staff. Melbourne includes the Parkville Precinct, the City and Carlton, but CSL is just outside in neighboring Brunswick.

This election, Ms Sandell has produced an \$87.8 million 'Respect Research' document.

It commits the Greens to \$56 million over four years for medical research commercialization and translation in Victoria, \$29.8 million for the construction of a Drug Discovery Centre, \$1.8 million to establish the Victorian Centre for Gender Equity in Science and \$200,000 "to conduct an inventory of Victoria's research capabilities and needs to become a world leader in anti-microbial resistance".

In terms of trial results, one can only conclude that Labor significantly outperforms Liberal ($p < 0.001$), and The Greens are a safe, optional, adjunct immunotherapy.

David Langsam
Editor

[DIMERIX](#)

Dimerix says the first of 10 patients has been dosed in its phase II clinical trial of DMX-200 for focal segmental glomerulosclerosis (FSGS) at Brisbane's Princess Alexandra Hospital. Dimerix said that FSGS was a rare disease of the kidney's filtering units, or glomeruli, causing scarring which led to kidney damage and failure.

The company said that patients would receive two 16-week treatment blocks separated by a six-week washout period receiving either placebo or DMX-200 in the first treatment block, then switching to the alternative in the second treatment block

Dimerix said that all participants would receive 300mg of irbesartan, the current standard of care, daily for at least three months prior to screening so that reductions in proteinuria, or blood in the urine, could be "solely attributed to the potential benefits of DMX-200".

The company said it expected results from this study and a separate phase II study of DMX-200 for diabetic kidney disease were expected by January 2020 (BD: Nov 19, 2018). "With both our FSGS and diabetic kidney disease trials dosing patients, the company has reached a key inflection point," Dr Webster said.

Dimerix was unchanged at 9.8 cents.

DORSAVI

Dorsavi says it has an agreement with Workright NW to use its wearable motion analysis devices for workers at a client company's Pennsylvania chemical plant.

Dorsavi said the agreement with the Woodland, Washington-based Workright NW was valued at \$106,000 and the program would run for 12 months with an option to extend to four years.

The company said that Workright NW would use Dorsavi's data-capturing and motion analysis technology for safety assessments and manual handling job analysis for more than 1,000 workers at the chemical plant.

Dorsavi said the aim of the project was to use "data insights" obtained using its motion analysis devices to assist in reducing the rate of musculoskeletal disorder injuries, such as muscle strain and mechanical back pain and improve workforce efficiency.

The company said the project combined its Visafe, Myvisafe and its clinical professional suite products to "deliver the most suitable program for Work Right NW's client".

Dorsavi fell 0.2 cents or 2.9 percent to 6.8 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has licenced injectable pentosan polysulfate sodium from New York's Icahn School of Medicine for muco-poly-saccharidoses.

Paradigm said that the inherited lysosomal storage disorder meant the body was unable to break down long chain sugar molecules and the build-up of the sugars in cells, blood and connective tissue could lead to a variety of health problems.

The company said that the cumulative incidence of all types of muco-poly-saccharidoses was about 3.5 per 100,000.

Paradigm chair Graeme Kaufman told Biotech Daily the company had "exclusive rights to pentosan polysulfate sodium for a range of indications including licences from third parties as well as internally generated intellectual property".

"This one is licenced from Icahn," Mr Kaufman said.

In its media release to the ASX, the company said that a "key unmet medical need in this class of inherited disease is the lack of treatment of joint pain and dysfunction akin to osteoarthritis".

Paradigm said that the licence agreement included phase IIa trial data which was "very complementary and synergistic" to its osteoarthritis and bone marrow oedema, or bone bruising, program and was "a logical and valuable addition to Paradigm's product pipeline and [intellectual property] portfolio at this time".

The company said that the licence included a single-digit royalty to Icahn and provided granted patents in the US, Japan, Europe, Australia and New Zealand and the phase IIa trial demonstrated "excellent safety and strong efficacy data", including long-term safety in very sick and debilitated patients with chronic joint pain, which would be included in future US Food and Drug Administration submissions for its primary indications of osteoarthritis and bone bruising.

Paradigm said it expected fast-track approval following a pivotal phase IIb clinical trial.

The company said the new indication would be included under its exclusivity agreement for PPS with the Geretsried, Germany-based Bene Pharmachem.

Paradigm said the newly in-licenced indication was fully-funded for the next 12 months and beyond.

The company said its phase IIb osteoarthritis and bone bruising trial head-line results were expected by the end of 2018.

Paradigm was up four cents or 4.55 percent to 92 cents.

NUHEARA

Nuheara says it has partnered with Dublin's Hidden Hearing to provide make its Iqbuds Boost at 61 clinics in the Republic of Ireland by December 1, 2018.

In April, Nuheara said Boost was a "game-changing accessible hearing [product]" providing hearing assistance, music and hands-free phone calls (BD: Apr 24, 2018).

At that time, the company said that at \$649, Boost was about 10 percent of the cost of traditional digital hearing products, with mobile telephone application support available.

Today, Nuheara chief executive officer Justin Miller said that Hidden Hearing was "the first hearing healthcare chain to embed our Iqbuds Boost product on a country wide basis".

"This partnership will also allow Nuheara to conduct nationwide co-marketing, with the knowledge that anyone will be able to find Iqbuds Boost in any Hidden Hearing clinic... a significant marketing development in our global retail strategy," Mr Miller said.

Nuheara was up 0.2 cents or 2.8 percent to 7.3 cents with 3.8 million shares traded.

MEMPHASYS

Memphasys says it has an agreement with France's Genetics, Reproduction and Development laboratory to validate its Felix sperm separation system device.

Memphasys said a male infertility and andrology research team at the Clermont-Ferrand-based Genetics, Reproduction and Development (Gred) laboratory led by Prof Joel Dreve would collaborate with Memphasys scientific advisor and Felix co-inventor Prof John Aitken to conduct in-vivo clinical validation of the Felix device.

The company said the Gred team would collaborate with Prof Aitken to "validate the Felix system and confirm its application and efficacy in separating spermatozoa under clinical conditions from a range of clinical samples of human semen".

In October, Memphasys said the Stockholm, Sweden-based Anova Karolinska was the first to assess the Felix system (BD: Oct 22, 2018).

The company said that it expected the clinical validation programs to begin by April, 2019 and take six months to complete.

Memphasys was up 0.1 cents or 2.8 percent to 3.7 cents.

MGC PHARMACEUTICALS

MGC has earned a remuneration report first strike with the annual general meeting defeating the resolution 81,915,898 votes (53.5%) to 71,199,704 votes (46.5%).

Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill, and if passed, the directors must stand for re-election within 90 days.

MGC said that all resolutions faced dissent with 32.8 percent against the prior issue of options to advisors, 28.3 percent against the prior issue of placement shares, 15.6 percent against the 10 percent placement capacity and 14.4 percent opposed to the re-election of executive chairman Brett Mitchell as a director.

The company said that the resolution approving the disposal of MGC Derma was withdrawn as it was "no longer required to seek shareholder approval to the transaction under ASX Listing Rule 11.4".

The company's 2018 annual report said it had 1,212,830,412 shares on issue, meaning that the votes against the remuneration report amounted to 6.75 percent of the company, sufficient to requisition extraordinary general meetings.

MGC was up 0.1 cents or 2.5 percent to 4.1 cents with 2.8 million shares traded.

PHARMAXIS

Pharmaxis says its annual general meeting voted 15.3 percent against the re-election of founding director Malcolm McComas, with a constitutional change dropped.

Pharmaxis said that 32,153,080 votes (15.28%) opposed Mr McComas with 177,192,522 votes (84.19%) in favor and 1,478,960 votes (0.71%) at the “proxy’s discretion”.

The company said that a special resolution, requiring a 75 percent majority, to renew the proportional takeover provisions of the constitution was withdrawn prior to the meeting.

Pharmaxis said it had “concluded that this special resolution would not receive the necessary level of votes for approval from the company’s shareholders”.

The company said that the grant of 690,000 free performance rights to chief executive officer Gary Phillips was opposed by five percent of vote with the remuneration report passed overwhelmingly.

Pharmaxis’ most recent Appendix 3B said it had 394,261,298 shares on issue meaning that the vote against Mr McComas, amounted to 8.2 percent of the company’s total shares on issue, sufficient to requisition extraordinary general meetings.

Pharmaxis was unchanged at 25.5 cents.

COCHLEAR

The Valley Forge, Pennsylvania-based Vanguard Group says it is no longer a substantial shareholder in Cochlear but has a holding of 2,884,714 shares (4.998%).

Yesterday, Vanguard said it had become a substantial shareholder in Cochlear with 2,886,647 shares (5.002%) (BD: Nov 21, 2018).

Today, the company said that on November 19, 2018 it sold 1,933 shares for \$156.03 a share, which Biotech Daily calculates makes its total holding 2,882,781 shares.

Cochlear was up \$4.63 or 2.85 percent to \$167.29 with 310,319 shares traded.

GENETIC SIGNATURES

Deutsche Bank’s Sydney branch says it has sold all 14,893,618 Genetic Signatures shares for \$8,489,362 or 57 cents a share.

In October 2016, Deutsche Bank said it had become a substantial shareholder in Genetic Signatures with 14,893,618 shares (14.24%) (BD: Oct 21, 2016).

In a separate announcement, the Cayman Islands and Hong Kong-based Karst Peak Select Master Fund and Adam Leitzes said they had become substantial shareholders in Genetic Signatures buying 18,934,528 (18.20%) shares for 57 cents a share.

Genetic Signatures was untraded at 54 cents.

THC GLOBAL GROUP (FORMERLY THE HYDROPONICS COMPANY)

THC Global says it has changed its name from The Hydroponics Company to THC Global Group after receiving shareholder approval.

THC said the change was approved at an extraordinary general meeting on November 15, 2018 and its ASX code would remain THC.

THC was up 1.5 cents or 2.9 percent to 52.5 cents.