

# **Biotech** Daily

## Wednesday May 31, 2017

## Daily news on ASX-listed biotechnology companies

- \* ASX, BIOTECH FLAT: NEUREN UP 12%, UNIVERSAL BIO DOWN 12%
- \* PROTAGONIST, J&J \$1.3b PTG-200 CROHN'S DISEASE DEAL
- \* MEDADVISOR SIGNS SIGMA'S DISCOUNT DRUG STORES
- \* CSIRO SOFTWARE FOR EARLY CANCER DETECTION
- \* KENYA APPROVES ATOMO HIV SELF-TEST
- \* PHOSPHAGENICS LOSES 3<sup>rd</sup> DIRECTOR DR CAUWENBERGH PRE-AGM
- \* PHOSPHAGENICS 28% 1<sup>st</sup> STRIKE AGM
- \* US, EU PATENTS FOR NEUREN TROFINETIDE FOR AUTISM DISORDERS
- \* NUHEARA, WIDEX DEAL FOR BLOOM HEARING IQBUDS SALES
- \* REPRODUCTIVE HEALTH REQUESTS CAPITAL RAISING TRADING HALT
- \* CAMERON JONES REPLACES ADALTA CO SEC IAN HOBSON

#### MARKET REPORT

The Australian stock market edged up 0.12 percent on Wednesday May 31, 2017 with the ASX200 up 6.7 points to 5,724.6 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 14 fell, 11 traded unchanged and two were untraded.

Neuren was the best, up 0.7 cents or 12.1 percent to 6.5 cents with 1.6 million shares traded. Dimerix climbed 6.7 percent; Cyclopharm and Opthea rose more than four percent; Prima was up 3.3 percent; Acrux and Bionomics rose two percent or more; Factor Therapeutics and Pharmaxis were up more than one percent; with Cochlear, Medical Developments, Nanosonics and Sirtex up by less than one percent.

Universal Biosensors led the falls, down five cents or 12.2 percent to 36 cents with 234,817 shares traded. ITL and Orthocell lost more than six percent; Actinogen fell 5.4 percent; Living Cell fell 4.2 percent; Cellmid and Viralytics were down more than three percent; Avita and Prana shed more than two percent; Admedus, Compumedics, CSL, Reva and Starpharma were down one percent or more; with Clinuvel down 0.7 percent.

## PROTAGONIST THERAPEUTICS, JOHNSON & JOHNSON

Protagonist says it has an up-to \$US990 million (\$A1,327 million) deal with Janssen Biotech for its PTG-200 for Crohn's disease.

The Brisbane-founded, Newark, California-based and Nasdaq-listed Protagonist said the agreement with the Johnson & Johnson subsidiary included a \$US50 million upfront payment and potentially up-to an additional \$US940 million in development and sales milestones; double-digit tiered royalties on net sales (BD: Aug 12, 2016).

Protagonist said that two companies would co-fund development of the pre-clinical stage, PTG-200 first-in-class, oral peptide, IL-23 receptor antagonist for inflammatory bowel disease, including Crohn's disease, to the completion of phase II clinical trials, with the drug expected to enter phase I trials in healthy volunteers by the end of 2017.

Protagonist said the agreement built on 2013 financing by Johnson & Johnson Innovation. Protagonist chief executive officer Dr Dinesh Patel said that Janssen was "a world-leader in the development of innovative therapies for patients suffering with chronic inflammatory and immune-modulatory diseases".

"As an oral IL-23 receptor antagonist, PTG-200 nicely complements Janssen's current [inflammatory bowel disease] portfolio," Dr Patel said.

Dr Patel said that the transaction enables Protagonist to advance its platform and clinical pipeline of peptide drugs, including the lead oral peptide alpha-4-beta-7 integrin antagonist PTG-100 which was in a phase IIb trial for ulcerative colitis.

Protagonist chief scientific officer Dr David Liu said that PTG-200 worked by blocking the IL-23 pathway "a mechanism which has been proven by injectable antibodies, including an approved drug and others in different stages of clinical development".

Protagonist said the development milestones would be significant payments on completion of each component of the phase IIa/IIb clinical trial in Crohn's disease if Janssen elected to retain its licence following each of those events.

The company said that Janssen would receive exclusive, worldwide rights to develop and commercialize PTG-200 and the two companies would jointly conduct the development of PTG-200 to the end of phase II clinical proof-of-concept in Crohn's disease, after which Janssen would be responsible for development and commercialization.

The company said it expected the agreement to be completed by October 2017.

On the Nadsaq, Protagonist was up \$US3.43 or 41.7 percent to \$US11.65 (\$A15.62) with 3.2 million shares traded.

#### **MEDADVISOR**

Medadvisor says it has partnered with Sigma Healthcare's Discount Drug Stores to use its drug prescription reminder service.

Medadvisor said that the mobile telephone application connecting patients to pharmacies would be in a "white label" format at the Discount Drug Stores, adding the Sigma branding to the application.

The company said that the agreement added a further 100 pharmacies and about 50,000 users to its subscription reminder service.

Medadvisor said that Discount Drug Stores would be able to offer its customers a medication management product including script reminders, tap-to-refill capabilities and an ability to digitally connect with their doctor through the platform.

Medadvisor chief executive officer Robert Read said that the Discount Drug Stores "decision to adopt our premium product and white label the Medadvisor [application] for their customers reflects the flexibility in our approach".

Medadvisor was unchanged at three cents with 1.75 million shares traded.

## COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

The Commonwealth Scientific and Industrial Research Organisation says it is developing a blood vessel formation algorithm for an early diagnosis of cancer.

The CSIRO said its Data61 researchers were working on an algorithm to detect the early formation of blood vessels, or angiogenesis, which could lead to early diagnosis of malignant tumors and improved success rates of treatment

The Organisation said that the development of new blood vessels preceded the growth of cancers and earlier detection of blood vessel growth could lead to a faster diagnosis of malignant tumor growth, a factor in successful treatment and patient survival.

The CSIRO said that Data61 researchers and staff from the Shanghai Institute of Applied Physics produced images of the brains and livers of mice at various stages of cancer growth and developed an algorithm to generate a representation of the vasculature, preserving the length and shape information of the blood vessel and its branches.

The Organisation said that the work was done using "end-point constraints ... [which were] critical in preserving the geometrical features of new blood vessels, including branching patterns and the lengths of terminal vessels".

The CSIRO said that until now, images of blood vessel structure taken from highresolution imaging could only produce a skeletonised view of blood vessel structure which provided limited detail and accuracy, but the accurate quantification of vasculature changes, particularly the number of terminal vessel branches, could play a critical role in accurate assessment and treatment.

The Organisation said that anti-angiogenesis treatment aimed at preventing cancers from growing blood vessels and the ability to continuously monitor subtle proliferations in blood vessels over time was essential, given that patients might react to anti-angiogenesis treatment differently.

The CSIRO said that the new software allowed researchers to measure subtle changes in the proliferation of blood vessels, including the number and length of the blood vessel branches, and produced significantly clearer skeletons of the vasculature than previously possible.

Cancer Council Australia chief executive officer Prof Sanchia Aranda said that the threedimensional synchrotron images of the vessels would advance the understanding of cancer progression.

"The hope is that through improved understanding new opportunities to disrupt angiogenesis will be identified and open pathways to new treatments," Prof Aranda said. The CSIRO Data61's quantitative imaging lead researcher Dr Dadong Wang said the applications of the software could be extended beyond three-dimensional angiogenesis analysis.

"Our robust algorithms for the early detection and quantification of angiogenesis could potentially be a great step forward in the detection and treatment of cancer," Dr Wang said.

"However, they can also be applied to a wide range of other applications, such as analysis of [three-dimensional] neurite outgrowth for drug development," Dr Wang said.

"While there is great interest in taking these findings further, there is still a long way to go before this new development can be applied to human patients," Dr Wang said.

But we are very hopeful, and currently looking for collaborators and partners to take the technology to the next stage," Dr Wang said.

## **ATOMO DIAGNOSTICS**

Atomo says the Kenya's Ministry of health has approved its HIV self-test product. Atomo said that the HIV Self Test had been evaluated by the Kenya Medical Research Institute in Nairobi and received a certification of registration from the Kenya Ministry of Health, Pharmacy and Poisons Board.

The company said that the test had "a built-in safety lancet and a unique blood collection and delivery system that make it easy to use and help to eliminate errors common with traditional multi-component ... kits".

Atomo said the test required a drop of fingertip blood and provided the result in 15 minutes.

The company said that trialled with "untrained lay users" the Atomo HIV Self Test was able to detect 100 percent of HIV infections in two separate studies.

Atomo said the Kenya Institute recommended the test be used to enable the national HIV testing program "to benefit from its superior usability and in-field performance".

Atomo founder and chief executive officer John Kelly said the company was "extremely pleased" the test had been approved in Kenya".

Atomo said that Kenya was "at the forefront of HIV self-testing in Africa and formally launched its HIV self-testing campaigns this month".

The company said that there were about 1.5 million people living with HIV in Kenya, with an estimated 400,000 people unaware they have the virus.

Atomo said there was a high prevalence of new infections, particularly amongst young people and key populations and it was believed that 8,000,000 million adults in Kenya had not been tested for HIV, with most seeking healthcare services in the private sector where HIV testing was not routine.

The company said that improving HIV testing among high risk groups was central to controlling the spread of HIV infection, with early diagnosis enabling faster access to life-saving treatments.

Atomo is a private company.

#### **PHOSPHAGENICS**

Phosphagenics says non-executive director Dr Geert Cauwenbergh has resigned "to concentrate on his other business commitments".

Phosphagenics chairman Dr Greg Collier said Dr Cauwenbergh "contributed significantly to the company's progress and we wish him well in all of his future endeavours".

The company said that two items of business relating to Dr Cauwenbergh's election and the issue of 1,500,000 options for today's annual general meeting had been withdrawn. At last year's annual general meeting Phosphagenics narrowly escaped a remuneration report second strike, gained David Segal as a director it opposed and lost director Nathan Drona who it wanted (BD: May 19, 2016).

In 2016, the company said that the election of David Segal was supported by 67.8 percent of the votes, which amounted to 21.6 percent of all shares on issue.

On the morning of the annual general meeting Phosphagenics said Mr Drona had "decided to step down from the board to focus on his other business interests and commitments".

In 2015, chairman Lawrence Gozlan resigned six days ahead of the annual general meeting, which sustained a first strike remuneration report vote (BD: May 12, 19, 2015). Phosphagenics did not provide the proxy votes for the withdrawn resolution and at the time of publication had not responded to a request from Biotech Daily for those votes. Phosphagenics was unchanged at 1.7 cents.

#### PHOSPHAGENICS

Phosphagenics says that its annual general meeting has recorded a remuneration report first strike with 27.73 percent opposing the report (BD: Apr 28, 2017).

In 2015, Phosphagenics failed to change its name to Alyptus Biotechnology and earned a remuneration report first strike (BD: May 19, 2015).

The 2015 name change special resolution required 75 percent support, but was opposed by 31.94 percent of votes and supported by 68.05 percent, with the remuneration report opposed by 32.79 percent and supported by 67.21 percent.

Last year the Phosphagenics annual general meeting narrowly passed the remuneration report resolution with 77.2 percent in favor and 22.8 percent against, but lost its preferred director Nathan Drona, who resigned on the morning of meeting, and gained David Segal which the board opposed (BD: May 19, 2016).

Today, Phosphagenics said that 291,482,368 votes (72.27%) supported the remuneration report, but 111,818,760 votes (27.73%) opposed it.

The company said that despite significant dissent all other resolutions passed, with up to 97,921,837 votes (25.84%) opposing 1,500,000 options for Peter Lankau.

The company did not disclose the distribution of "proxy discretion" votes except for the remuneration report.

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 at the later meeting and if passed by more than 50 percent of votes the directors must stand for re-election at a subsequent meeting within 90 days.

Phosphagenics most recent Appendix 3B new issue announcement said that the company had 1,261,965,957 shares on issue, meaning that the votes against the remuneration report amounted to 8.9 percent of the company, sufficient to requisition extraordinary general meetings.

## NEUREN PHARMACEUTICALS

Neuren says a US and European patent have been approved relating to the use of trofinetide for autism spectrum disorders and providing protection until January 2032. Neuren said that the US Patent and Trademark Office had allowed a patent entitled 'Treatment of Fragile X Syndrome Using [G-2-MePE]' covering the use of trofinetide for Fragile X syndrome.

The company said that a similar patent covering its use in Rett syndrome was issued in December 2015.

Neuren said that the European Patent Office intended to grant a patent entitled 'Treatment of Autism Spectrum Disorders Using [G-2-Me-PE]' relating to the use of trofinetide to treat autism spectrum disorders, which include Rett syndrome and Fragile X syndrome.

The company said that trofinetide was covered by composition of matter patents in the US and Europe, which expire in 2022, with the potential to extend to 2027.

Neuren said it had an Australian patent covering the use of trofinetide to treat autism spectrum disorders and similar patent applications pending in Japan, Canada, Brazil and Israel.

The company said it had orphan drug designation in the US and the European Union for both Rett syndrome and Fragile X syndrome, providing market exclusivity following authorization of seven years in the US and 10 years in the European Union.

Neuren was up 0.7 cents or 12.1 percent to 6.5 cents with 1.6 million shares traded.

#### <u>NUHEARA</u>

Nuheara says it has entered a retail partnership with Widex Australia for its Iqbuds to be sold at Bloom Hearing clinics in Australia.

Nuheara said that Bloom provided audiological services at more than 240 locations in Australia and was owned by the Lynge Denmark-based Widex, one of the world's largest and leading hearing aid manufacturers.

The company said that lqbuds were a multi-functional hearing device for a range of problems for differing generations.

Nuheara was unchanged at 7.6 cents with 7.4 million shares traded,

#### REPRODUCTIVE HEALTH SCIENCE

Reproductive Health has requested a trading halt "pending an announcement to the market regarding a proposed capital raise".

Trading will resume on June 2, 2017 or on an earlier announcement.

Reproductive Health last traded at 15.5 cents.

## <u>ADALTA</u>

Adalta says it has appointed Cameron Jones as company secretary and chief financial officer replacing company secretary Ian Hobson, effective from today.

Adalta said that Mr Jones was a director of Biotech Capital subsidiary Bio101 Group Pty Ltd and previously worked for Pitcher Partners.

Adalta was untraded at 30 cents.