



# Biotech Daily

Thursday October 27, 2016

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH DOWN: ORTHOCELL UP 6%; ONCOSIL DOWN 13%**
- \* **FEDERAL GOVERNMENT \$190m for 320 NHMRC GRANTS**
- \* **GATES FOUNDATION \$3.6m FOR ATOMO HIV TEST**
- \* **USCOM MONITOR 'GUIDES PAEDIATRIC SEPTIC SHOCK TREATMENT'**
- \* **DORSAVI US LOW BACK PAIN REGISTRY FOR TREATMENT, PAYMENT**
- \* **NUHEARA RAISES \$5m FOR IQBUDS**
- \* **STREULI TO DISTRIBUTE CRESO MARIJUANA GUM IN SWITZERLAND**
- \* **MAYNE US LAUNCH OF GENERIC ENTOCORT EC FOR CROHN'S DISEASE**
- \* **VITTORIA TO DISTRIBUTE RHINOMED MUTE, TURBINE PLUGS IN US**
- \* **ADHERIUM FACES 14% DISSENT TO 2.6m DIRECTOR LOAN SHARES**
- \* **PAUL RUGGIERO, 'LIKE-MINDED INVESTORS' BELOW 5% OF CELLMID**
- \* **PHARMAXIS AGM FOR 827k MORE CEO 'PERFORMANCE RIGHTS'**
- \* **AVITA \$366k DIRECTORS SHARES IN LIEU OF PAY AGM**
- \* **IDT REQUESTS 'CORPORATE TRANSACTION' TRADING HALT**
- \* **PATRYS PLEADS SCHULTZ TO ASX 33% QUERY**

## MARKET REPORT

The Australian stock market fell 1.2 percent on Thursday October 27, 2016 with the ASX200 down 64.3 points to 5,295.5 points. Thirteen of the Biotech Daily Top 40 stocks were up, 19 fell, five traded unchanged and three were untraded. All three Big Caps fell.

Orthocell was the best, up 2.5 cents or 5.95 percent to 44.5 cents with 180,864 shares traded. Starpharma climbed 5.2 percent; Benitec, Neuren and Prana were up more than four percent; Admedus and Avita improved more than three percent; Mesoblast rose 2.65 percent; Genetic Signatures, Pharmaxis and Polynovo were up more than one percent; with Clinuvel and Ellex up by less than one percent.

Oncosil led the falls, down 1.5 cents or 13.0 percent to 10 cents with 1.9 million shares traded. Compumedics lost 7.9 percent; Actinogen shed 6.7 percent; Viralytics fell 5.7 percent; Cyclopharm was down 4.2 percent; Atcor, Factor Therapeutics, Impedimed and Osprey were down more than three percent; Medical Developments shed 2.8 percent; with Anteo, Bionomics, Cochlear, CSL, Living Cell, Pro Medicus, Resmed, Reva, Sirtex and Universal Biosensors down more than one percent.

## FEDERAL GOVERNMENT NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL

The Federal Government says the National Health and Medical Research Council will provide \$190 million for 320 health and medical research grants.

A media release from Health Minister Sussan Ley said that the funding included \$58 million to support research fellowships and \$38 million to fund early career fellowships. Ms Ley said that the grants “play a vital role in funding new research for treatments of diseases that affect Australians”.

The media release said that the funding included \$10.6 million for Aboriginal and Torres Strait Islander health research, \$2.5 million for a Centre of Research Excellence to build indigenous research capacity and to find solutions to alcohol-related health problems, as well as three early career fellowships for indigenous researchers.

Ms Ley said the grants would help Australia’s research community make discoveries that improved the diagnosis, treatment and cure of illnesses that affected indigenous Australians.

“We know there is much work to be done with Indigenous health outcomes,” Ms Ley said. “This government is committed to making long-term improvements in indigenous health and providing opportunities for Aboriginal and Torres Strait Islander researchers,” Ms Ley said.

The media release said that the funding was part of the NHMRC commitment to expend at least five percent of its budget to support research to improve the health of Aboriginal and Torres Strait Islander peoples.

The Federal Government media release said that more information on the grants was available at <https://www.nhmrc.gov.au/grants-funding/outcomes-funding-rounds>.

## ATOMO DIAGNOSTICS

The Sydney-based Atomo says the Bill & Melinda Gates Foundation has granted it a further \$US2.6 million (\$A3.6 million) to develop an HIV self-test.

Atomo said it had received a total of \$US10.6 million from the Bill & Melinda Gates Foundation and the Global Health Innovation Fund over the past year.

The company said that its major investors included Lang Walker and former Macquarie Bank chief Allan Moss (BD: Aug 11, 2016).

Atomo said that the grant would “support development of an affordable, reliable and simple HIV rapid diagnostic test that will enable people in resource-poor countries to test themselves”.

The company said that the consensus of the global health community was that HIV self-testing had potential to reach untested populations that were not accessing existing facilities-based testing services, particularly those at high risk of HIV infection that require more frequent testing.

Atomo chief executive officer John Kelly said the company had sought to develop “simple, low-cost solutions that remove errors common with the current generation of bits-in-a-box test kits” and its device removed the need for multiple test components, making it simpler, safer and more convenient.

Atomo said that more than 120 million HIV rapid diagnostic tests were used each year in resource-poor countries and demand for testing was projected to increase significantly until 2020.

Atomo is a public unlisted company.

## USCOM

Uscom says its technology guided therapy in a study of haemodynamics during the early administration of nor-epinephrine for septic shock.

Uscom said that the research demonstrated “improved outcomes by using American Society of Critical Care Medicine guidelines and Uscom 1A guided advanced haemodynamics during the early administration of nor-epinephrine”.

The research article, entitled ‘Early norepinephrine decreases fluid and ventilatory requirements in paediatric vasodilatory septic shock’ was published in the Indian Journal of Critical Care Medicine and is available at: <http://bit.ly/2dYgnex>.

Uscom executive chairman Prof Robert Phillips told Biotech Daily that the ultra-sonic cardiac output monitor 1A (Uscom 1A) was used throughout the study.

“All the critical measurements in the study were done by Uscom, including cardiac pre-load, cardiac function and after-load,” Prof Phillips said.

Uscom said that the study found that early nor-epinephrine and Uscom 1A-guided advanced haemodynamics, when added to current best practice for treating persistent vasodilatory septic shock in children, found a 75 percent reduction in invasive ventilation, a 33 percent reduction in paediatric intensive care days and a 58 percent reduction in fluid use, when added to current using American Society of Critical Care Medicine (ACCM) guidelines and ultra-sound echo-cardiogram monitoring.

The company said that the reduction in paediatric intensive care days from six days to four days reduced the cost of care for each child by an about US\$9,032 or \$US4,516 a day.

Uscom said its monitor was used “as an accurate monitor of cardiovascular function, which is often impaired in sepsis and septic shock and was used to guide the implementation of appropriate cardiovascular therapy, including nor-epinephrine, fluids, inotropes and vaso-actives”.

The company said that the research in children one month old to 16 years, was performed at the Apollo Hospital in Chennai and was authored by some of the world’s leading clinical researchers on critical care medicine and septic shock.

Prof Phillips said that “leadership in science is our Uscom mission and improved outcomes, particularly in children, the measure of our success”.

“Sepsis is one of the dominant diseases of our time and increasing in incidence as infections become more common and antibiotic resistant,” Prof Phillips said.

“Ultimately death in sepsis is from circulatory failure so management of cardiovascular function is vital and Uscom 1A is the most simple, most accurate and rapid method we have and its increased use is proving to significantly improve outcomes and will reduce the use of invasive catheterisation,” Prof Phillips said.

“This outcomes study by global key opinion leaders demonstrates that Uscom 1A use is associated with improved outcomes in paediatric sepsis, a disease responsible for approximately 70 percent of all childhood deaths worldwide,” Prof Phillips said.

“These results provide further evidence of the effectiveness of our technology, which is becoming standard of care in the world’s best paediatric hospitals,” Prof Phillips said.

“The first three authors on the ACCM Paediatric Sepsis Guidelines use Uscom 1A for the management of sepsis,” Prof Phillips said.

“This publication is important evidence for our global distributors and suggests that Uscom 1A should be included in global guidelines for treatment of paediatric sepsis in healthcare systems worldwide,” Prof Phillips said.

The company said that severe sepsis accounted for about “eight percent of paediatric intensive care unit admissions and 33 percent of all paediatric intensive care deaths in the US, a figure likely to be much higher in developing nations”.

Uscom was unchanged at 25 cents.

## DORSAVI

Dorsavi says the first low back pain patient has been recruited into its US-based back pain and movement registry.

Dorsavi said the registry would recruit 1,500 low back pain patients in the first 18 months to establish a better understanding of the relationship between body movement, muscle activity, physical function and a range of other factors associated with low back pain.

The company said that total costs related to low back pain in the US was more than \$US100 billion a year, with insurers and payers looking for effective treatments to reduce the economic burden and improve patient wellbeing.

Dorsavi said that the registry was “an important component in [its] reimbursement strategy” and the steering committee was headed by Washington DC-based physical medicine and rehabilitation physician Dr Mehul Desai.

Dr Desai’s practice and Synergy Manual Physical Therapy were the first two registry sites with more sites being recruited, with ethics approval provided by the George Washington University Institutional Review Board.

Dr Desai said that the registry findings would provide “an increased understanding of low back pain, creating an opportunity to deliver more targeted and earlier interventions that are more likely to be successful”.

Dorsavi fell eight cents or 15.7 percent to 43 cents.

## NUHEARA

Nuheara says its oversubscribed placement at six cents a share has commitments to raise \$4,984,00 from institutional and sophisticated investors.

Nuheara said that the proceeds would be used to fund the production and marketing of its lqbuds sound filtering and device ear buds.

Nuheara chief executive officer Justin Miller said that the funds would “vastly increase Nuheara’s global reach, supply and sales potential”.

The company said that Foster Stockbroking and Aetas Global Markets were co-lead managers to the placement.

Nuheara fell 1.3 cents or 16.05 percent to 6.8 cents with 9.6 million shares traded.

## CRESO PHARMA

Creso says it has an agreement with the Uznach, Switzerland-based Streuli Pharma to commercialize its first human food product Innutri Soft Gums in the Swiss market.

Creso said that Streuli manufactured more than 150 million tablets and capsules a year.

The company said that its Innutri Soft Gums used “an innovative and proprietary delivery technology for optimum delivery of cannabis and hemp derived therapeutic products”.

Creso said that the cannabis was delivered through buccal, or mouth, absorption and the soft-gums had advantages over existing health supplement products.

The company said that the gums were easier to ingest than gelatin-based products, were starch-based, 60 percent cheaper than gelatin capsules and were vegan, halal and kosher as well as gluten-free, lactose-free and ideal for paediatric and geriatric use.

Creso said it intended to pursue partnerships for the sale of the Innutri Soft Gums across Europe, Canada, Latin America and the Arabian Gulf states.

Creso chief executive officer Dr Miri Halperin Wernli said the food additive market was “a significant opportunity for Creso and we expect demand for our human health products to be strong given the growth in the European market”.

Creso fell 1.5 cents or 4.8 percent to 30 cents with 2.9 million shares traded.

## MAYNE PHARMA GROUP

Mayne Pharma says it has launched a generic version of 3mg Entocort EC, or budesonide capsules in the US for patients with mild to moderate Crohn's disease. Mayne said that brand and generics sales of budesonide capsules were about \$US322 million for the 12 months to August 31, 2016.

Mayne chief executive officer Scott Richards said the launch added "another quality product to our on-market portfolio of generic pharmaceuticals".

Mr Richards said that the product was part of the recent generic product acquisition from Teva Pharmaceutical and Allergan, which would be manufactured at our facility in Salisbury, South Australia.

Mayne fell 2.5 cents or 1.45 percent to \$1.705 with 5.1 million shares traded.

## RHINOMED

Rhinomed says that sports distributor Vittoria Industries North America will distribute its Mute anti-snoring and Turbine sports nasal plugs in the US.

The Boston, Massachusetts-based parent company Vittoria manufactures and distributes bicycle tyres and wheels.

Rhinomed said that the agreement would open new sales avenues for Turbine at independent bike shops, through online electronic commerce and "high-growth niche markets such as yoga, health and fitness clubs".

The company said that Vittoria would import stock and its 34-staff sales force would introduce the Turbine plugs to its more than 4,000 accounts across the US.

Rhinomed said the existing partnership with Europa Sports would continue with the Mute technology alone and Vittoria would support Mute's entry into "the impulse buy retail market" through specific targeting of high traffic retail locations such as airport convenience shops, cruise ships, hotel chains, yoga centres and health and fitness club networks.

Rhinomed was up 0.2 cents or 10 percent to 2.2 cents with 3.2 million shares traded.

## ADHERIUM

Adherium's annual general meeting passed all resolutions but with up to 13.7 percent dissent against resolutions to lend directors funds to buy 2,621,367 shares.

The Adherium notice of meeting said that loans would be provided to chairman Thomas Lynch to acquire 600,000 shares at 50 cents each, with a further 300,000 shares each to directors Prof John Mills, Dr William Hunter, Jeremy Curnock Cook, Bruce McHarrie and Bryan Mogridge, along with \$260,684 to chief executive officer Garth Sutherland to acquire 521,367 shares (BD: Sep 26, 2016).

Adherium's meeting results showed that all seven resolutions faced similar levels of dissent with the strongest opposition vote of 11,597,148 votes (13.7%) to 72,845,489 votes (86.3%) in favor of providing the loan shares to Prof Mills and Mr McHarrie.

All other resolutions, including the increase of the aggregate fee pool for non-executive directors by 42.9 percent to \$500,000 a year, were passed overwhelmingly.

The company's most recent Appendix 3B said that Adherium had 133,686,097 shares on issue meaning that the opposition to Prof Mills and Mr McHarrie's loan shares amounted to 8.7 percent of the company's total shares on issue, sufficient to requisition extraordinary general meetings.

Adherium was up one cent or 2.9 percent to 35 cents.

### CELLMID

The Gladesville, Sydney-based Paul Ruggiero says that the “association of like-minded investors” has withdrawn and the group no longer has a substantial holding in Cellmid. In June and July, Mr Ruggiero said he was the Association’s “group coordinator” and named about 20 shareholders holding 145,221,267 shares (15.6%) (BD: Jul 18, 2016). Cellmid was untraded at 3.3 cents.

### PHARMAXIS

Pharmaxis shareholders will vote to grant chief executive officer Gary Phillips 827,000 free ‘performance rights’ vesting in two tranches.

Last year, Pharmaxis investors voted 8.9 percent dissent against the issue of 1,626,000 performance rights to Mr Phillips, with 91.1 percent in favor (BD: Oct 16, 2015).

The opposition represented 2.2 percent of the shares on issue.

Today, the Pharmaxis notice of annual general meeting said that shareholders would vote to approve the remuneration report and re-elect chairman Malcolm McComas.

The meeting will be held at the Christie Conference Centre, 3 Spring Street, Sydney on November 29, 2016 at 2.30pm (AEDT).

Pharmaxis was up half a cent or 1.9 percent to 27 cents.

### AVITA MEDICAL

Avita shareholders will vote on the issue of 3,322,842 shares worth \$365,513 a year for three years to six directors “in lieu of all or some of their director’s fees”.

Avita said directors Lou Panaccio, Jeremy Curnock Cook, Michael Perry, Louis Drapeau, Damien McDonald and Suzanne Crowe would be offered the shares at 11.0 cents.

Avita said the meeting would vote on the remuneration report, the re-election of directors Mr Panaccio and Ms Crowe, the appointment of directors Mr Drapeau and Mr McDonald, the ratification of the prior issue of 2,156,039 options, the employee share plan, the employee incentive option plan and the approval of the 10 percent placement capacity.

The meeting will be held at Grant Thornton, Level 30, The Rialto, 525 Collins Street, Melbourne on November 29, 2016 at 10am (AEDT).

Avita was up half a cent or 3.7 percent to 14 cents.

### IDT AUSTRALIA

IDT has requested a trading halt “to finalize a possible corporate transaction”.

Trading will resume on October 31, 2016 or on an earlier announcement.

IDT last traded at 21.5 cents.

### PATRY'S

Patry's 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 33.3 percent from 0.75 cents to one cent on October 26, 2016, and noted a significant increase in trading volume.

Patry's fell 0.1 cents or 11.1 percent to 0.8 cents with 1.6 million shares traded.

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