



Thursday November 17, 2016

Daily news on ASX-listed biotechnology companies

- * ASX UP, BIOTECH DOWN: NEUREN UP 10.5%, BENITEC DOWN 9%
- * WEHI, MELBOURNE UNI ORGANOIDS BANK FOR PANCREATIC CANCER
- * IMPEDIMED SOZO FOR HEART FAILURE AVAILABLE IN 2017
- * VOLPARA, MICROSOFT COLLABORATE ON BREAST IMAGING ANALYTICS
- * SUDA: 'HYDROTROPES ENHANCE VIAGRA PERMEATION IN RABBITS'
- * CRESO TO MARKET CANNIMED'S MEDICAL CANNABIS IN EUROPE
- * MACH7 TO RELEASE 1.5m ESCROW SHARES
- * UP TO 20% OPPOSE LBT PLACEMENT CAPACITY
- * NOVOGEN 16% OPPOSE REMUNERATION REPORT
- * ANTHONY BARTON, ASSOCIATES TAKE 5% OF PHYLOGICA
- * MONASH'S PROF CHRISTOPOULOS, PROF SEXTON WIN \$80k GSK PRIZE
- * PROF IAN GUST WINS TOP RESEARCH AUSTRALIA GONG
- * NOXOPHARM APPOINTS THREE TRIAL ADVISORS, CONSULTANTS

MARKET REPORT

The Australian stock market was up 0.2 percent on Thursday November 17, 2016 with the ASX200 up 10.8 points to 5,338.5 points. Fourteen of the Biotech Daily Top 40 stocks were up, 20 fell, five traded unchanged and one was untraded.

Neuren was the best, up 0.6 cents or 10.5 percent to 6.3 cents with 3.3 million shares traded. Osprey climbed 9.1 percent; Atcor and Orthocell were up more than four percent; Admedus, Mesoblast, Nanosonics and Psivida rose more than two percent; Clinuvel, Compumedics, CSL, Opthea and Universal Biosensors were up by more than one percent; with Pro Medicus, Starpharma and Resmed up by less than one percent.

Benitec led the falls, down one cent or 9.1 percent to 10 cents with 24,612 shares traded. Prana lost 9.0 percent; Uscom shed 6.25 percent; Genetic Signatures and Living Cell fell four percent or more; Anteo and Medical Developments were down more than three percent; Acrux, Bionomics, Cyclopharm, IDT and Sirtex shed more than two percent; Factor Therapeutics, Impedimed, Pharmaxis and Polynovo were down more than one percent; with Airxpanders, Cochlear, Reva and Viralytics down less than one percent.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says research to improve pancreatic cancer survival will be assisted with Australia's first pancreatic cancer organoids bank.

WEHI said that five of its research teams in partnership with the University of Melbourne were establishing the bank "to reduce the time it takes to find the right treatment for patients from months to weeks".

The Institute said that organoids were "mini pancreatic organs the size of a grain of sand" which would be treated with up to 15 drugs used for pancreatic cancer and other cancers. WEHI's head of structural biology Prof Tony Burgess said the use of organoids would be a significant change from current drug testing techniques, which could take eight months to yield results that were unreliable.

"We expect organoids to give us answers on an individual patient's drug sensitivity and resistance in 10 days," Prof Burgess said.

"Combine that with information on each patient's genetic mutations, and we expect this will give doctors real answers inside three weeks," Prof Burgess said.

The University of Melbourne's Prof Sean Grimmond said clinicians had limited time to decide on treatment, as the average pancreatic cancer patient survived from three to six months after diagnosis.

"When that first round of chemo fails, we're up against the clock and the timeframes are ruthless," Prof Grimmond said.

"The end-game is to take the guesswork out of chemotherapy, with a clinical test that will assess dozens of drugs and drug combinations against tumor samples from each patient," Prof Grimmond said.

WEHI said the project would be housed at the Victorian Comprehensive Cancer Centre from 2017, with researchers hoping to reach the first trial phase of the project in 2018. The Institute said that the accelerated effort was made possible by a \$916,000 grant from the Sydney-based Avner Pancreatic Cancer Foundation to the University of Melbourne, which was providing about \$2 million for research intended "to double survival rates by 2020".

WEHI said that the five-year survival rate for pancreatic cancer was seven percent and the 10-year survival rate was one percent.

Avner Foundation co-founder and chief executive officer Caroline Kelly said the Foundation was "thrilled to award this grant to such a ground-breaking team".

"Our priority is to keep working to fund further research into this low profile but devastating cancer and increase survival rates," Ms Kelly said.

Ms Kelly told Biotech Daily that the Foundation, named after her husband Avner Nahmani who died from pancreatic cancer, had raised more than \$7 million for pancreatic cancer research.

WEHI said that the funding was part of the University of Melbourne's Believe campaign, which was "the largest ever fundraising commitment for an Australian public institution". The Institute said that Believe campaign aimed to raise \$1 billion by 2021, with health and wellbeing as a core focus.

WEHI said it wanted to recognise the leadership of Jane Hemstritch who in 2015 committed a \$1 million gift in memory of her husband Philip to advance pancreatic cancer research.

The Institute said that the Philip Hemstritch Pancreatic Research Program provided the impetus for this additional support from the Avner Foundation.

WEHI said that the funds "exemplify the impact of philanthropic support for under-funded research".

IMPEDIMED

Impedimed chief executive officer Richard Carreon says he expects both European and US regulatory approval for the Sozo fluid detection device in 2017.

Mr Carreon told a Melbourne investor and media conference that the company took 10 months to take the Sozo device from concept, through design and manufacture, to being "on the verge of submitting for EU clearance and completing the FDA submission".

Mr Carreon said that the EU clearance was expected in early 2017, with the US Food and Drug Administration submission to be lodged at the same time and approval expected by the end of 2017.

He said that no regulatory trials were required as the Sozo was using technology that could be approved by comparison to other existing technologies.

Mr Carreon said that the first application of the Soza would be to detect fluid changes in patients with class III congestive heart failure to prevent their readmission to hospital. He said that hospital readmissions were costly to the health system and in the US hospitals were penalised for patients returning within 30 days of discharge.

Mr Carreon said class III and class IV congestive heart failure patients were the focus of the US Medicare Hospital Readmission Reduction Plan and the Sozo was expected to detect the build-up of fluid from heart failure more accurately and less expensively than existing technologies.

He said the direct measure of fluid, fat, muscle and bone by the 256 frequencies used in the less than 15-second test allowed doctors to assess at-risk patients changes over time. Mr Carreon said that the tests were integrated with the patients' medical records and changes could be assessed and remedied early, preventing further deterioration and hospital readmission.

Impedimed chief strategy officer Jack Cosentino described the development of the Sozo and said that the internet "cloud" based system provided measurements over time, from segment to full body reporting.

Mr Cosentino said that the system was designed to be simple to use and easy to clean with stainless steel electrodes not requiring gels or patient shaving.

Mr Cosentino said the Sozo was designed with multiple potential uses beyond congestive heart failure and the home version could be used by multiple patients, logging-in under discrete identities.

Mr Carreon said that the hospital or clinic version of the Sozo would retail for \$US5,000 to meet US reimbursement requirements, while the home version would sell "for hundreds of dollars" but come with a monthly subscription.

He said that 5.7 million Americans had congestive heart failure and the company was targeting the 25 percent which had class III heart failure.

Mr Carreon said that with 1.4 million patients paying \$US60 a month the company's annual revenue would be more than \$1.0 billion a year.

"We believe we can be a game-changer," Mr Carreon said.

"Most money is spent on class III patients and if we can prove our point on class III we could pick up [the 35 percent of patients with] class II heart failure," Mr Carreon said. Mr Carreon said that clinical research with the Mayo Clinic and other hospitals was "for marketing purposes for clinical utility" and not required for the regulatory process. Mr Carreon said that L-Dex post-breast cancer lymphoedema test could be incorporated into the Sozo.

He said that 55 of 500 US cancer centres were using the L-Dex for lymphoedema assessment, which was expected to increase to 65 centres by the end of 2016 and up to 130 centres by the end of 2017.

Impedimed fell two cents or 1.4 percent to \$1.38 with 1.4 million shares traded.

VOLPARA HEALTH TECHNOLOGIES

Volpara says it has a collaboration with Microsoft for intelligent breast imaging analytics. Volpara said the collaboration would help imaging centres analyze clinical, quality and business data to optimize productivity, quality assurance and patient care.

The company said that Microsoft's Power BI Embedded tool-set would be integrated into its Volpara Enterprise system to enable facility managers to monitor the performance of their technologists and radiologists over time, ensuring consistent image quality vital to detect more cancers at an earlier stage.

Vopara chief executive officer Dr Ralph Highnam said the collaboration provided "greater flexibility in terms of licencing options and greater ease of integration with existing platforms ... [and] combined with the data, insights and quality control features that Volpara Enterprise already provides is expected to significantly boost the return on investment for breast screening clinics".

Volpara climbed 9.5 cents or 12.8 percent to 83.5 cents.

SUDA

Suda says its hydrotropes combination technology "can significantly enhance the permeation of active drugs through the oro-mucosal membrane into the blood system". Suda said that chief executive officer Stephen Carter presented the data on the penetration-enhancing technology at the Symposium of Drug Delivery Systems in Nanjing, China November 16 to 19, 2016.

The company said that hydrotropes were a class of compounds which increased the aqueous solubility of sparingly soluble solutes.

Suda said that hydrotropes were structurally defined as a molecule consisting of a polar and a non-polar end able to aggregate but unable to form micelles, or an aggregate of molecules in a colloidal solution.

The company said that a rabbit study to evaluate the permeation characteristics of the enhanced formulation of its SUD-003 sildenafil, marketed as Viagra, oral spray for erectile dysfunction, compared to the original formulation of SUD-003, the new technology resulted in a significant increase in the amount of active sildenafil drug that was absorbed. Suda said that further ex-vivo studies to test variations of the enhanced SUD-003 formulation suggested that the new technology could provide up to a 10-fold increase in the permeation of sildenafil.

Mr Carter said the company had "achieved significant improvements in the permeation characteristics of sildenafil and many other drugs using our hydrotrope technology". "Our new-generation formulation of SUD-003 could provide meaningful advantages over Viagra tablets for the treatment of erectile dysfunction," Mr Carter said.

Suda fell 0.1 cents or 4.2 percent to 2.3 cents with 4.8 million shares traded.

CRESO PHARMA

Creso says it has a letter of intent to market the Saskatoon, Saskatchewan-based Cannimed's medical cannabis brands in the European Union.

Creso said it would distribute Cannimed's products to governments, authorized importers and distributors, institutions, pharmacies and individuals.

The company said that several European countries including Germany and Denmark had moved to the legalization of medical cannabis when recommended by a physician, while Belgium and Austria had legislation in place to conduct clinical research.

Creso fell one cent or 3.6 percent to 27 cents.

MACH7 TECHNOLOGIES

Mach7 says that 1,500,000 shares will be released from held in voluntary escrow on November 30, 2016.

Mach7 company secretary Alyn Tai told Biotech Daily that following the issue of the 132,628,557 shares from yesterday's \$9 million placement and the release of the 1,500,000 shares, the company would have 581,689,924 shares available for trading. Ms Tai said there were 4,650,600 quoted shares in voluntary escrow and 500,681,174 unquoted shares in ASX escrow, making a total of 1,087,021,698 shares on issue. Mach7 fell 0.1 cents or 2.4 percent to four cents with 1.75 million shares traded

LBT INNOVATION

LBT's annual general meeting passed all resolutions easily, except the 10 percent placement capacity which was opposed by 20.3 percent of votes.

The placement capacity resolution was supported by 30,176,443 votes (79.5%) and opposed by 7,692,821 votes (20.3%) with 94,770 votes at the proxy's discretion.

The remuneration report, the re-election of chairman Bob Finder and the employee share option plan were passed overwhelmingly, with 413,687 votes opposing the issue of 1,500,000 options to chief executive officer Brent Barnes (BD: Oct 17, 2016).

LBT's most recent Appendix 3B new share issue announcement said it had 117,388,073 shares on issue meaning that the opposition to the placement capacity amounted to 6.55 percent of the company's total shares on issue, sufficient to requisition general meetings. LBT fell two cents or 4.1 percent to 46.5 cents.

NOVOGEN

All resolutions at the Novogen annual general meeting were passed, but with up to 16.4 percent opposition to the remuneration report and other resolutions.

Novogen said that following a poll the remuneration report received 194,845,577 votes (83.6%) in favor and 38,269,971 votes (16.4%) against, while the 10 percent placement capacity attracting the largest number of opposing votes with 39,349,929 votes (14.5%) against and 232,009,273 votes (85.5%) in favor.

The re-election of directors Steven Coffey and John O'Connor was opposed by more than 10 percent of voters at the meeting with the new constitution facing 4.5 percent opposition. The company's most recent Appendix 3B new issue announcement said Novogen had 467,287,914 shares on issue meaning that the largest opposition vote amounted to 8.4 percent of the company's total shares on issue, sufficient to requisition general meetings. Novogen was unchanged at nine cents.

PHYLOGICA

The Perth-based Anthony Barton says that with associates he has become a substantial shareholder in Phylogica with 100,500,000 shares (5.01%).

Mr Barton said the associated entities were Harvey Springs Estate, AP and CH Barton Superfunds, Barton and Barton and Inglewood Lodge and the shares were acquired on-market but failed to disclose the cost shares as required under the Corporations Act 2001. In its October annual report, Phylogica named AP and CH Barton as one of its top 20 shareholders with 28,000,000 shares or 1.40 percent and Harvey Springs Estate with a holding of 27,500,000 shares or 1.37 percent.

Phylogica was unchanged at 1.7 cents with 4.2 million shares traded.

GLAXOSMITHKLINE

Glaxosmithkline says that Monash University's Prof Arthur Christopoulos and Prof Patrick Sexton have won its \$80,000 award for research excellence.

Glaxosmithkline said that Prof Christopoulos and Prof Sexton were researching G proteincoupled receptors (GPCRs) to understand the complexities of drug action that could lead to more targeted medicines.

The company said that the allosteric site of a protein, allowed the targeted protein to be dialled up or down in a way that was not previously possible and the use of "dimmer switch" medicines could help patients with obesity, diabetes and schizophrenia, with drugs that can be turned up or down rather than on and off.

RESEARCH AUSTRALIA

Research Australia says that Prof Ian Gust has won the Peter Wills Medal for "a lifetime of discoveries, including the hepatitis A vaccination".

Research Australia said that the Advocacy Award was won by SIDS Stampede's Brenda King for her efforts to raise support and funding for sudden infant death syndrome laboratory research at Sydney's Westmead Children's Hospital; the Griffith University Discovery Award was awarded to the University of Queensland's Dr Rebecca Coll for her work in human inflammatory diseases; Dr Felicity Davis and Dr Michael Livingston were highly commended; the Great Australian Philanthropy Award was presented to the McCusker Charitable Foundation, which had raised \$50 million for research in Western Australia; the Capital Markets CRC Health Market Quality Team won the Data Innovation Award; the National Breast Cancer Foundation and the Vodafone and Garvan Institute of Medical Research collaboration, Dreamlab, were commended; the Leadership in Corporate Giving Award was won by Volvo Car Australia for fundraising and support of the Cure Brain Cancer Foundation; and the Ingham Institute for Applied Medical Research's Prof Michael Barton won the New South Wales Health Services Research Award for making cancer treatments more accessible.

NOXOPHARM

Noxopharm says it has appointed Prof Paul de Souza as medical advisor, with Prof Thomas Eade and Prof George Hruby as radiation oncology consultants. Noxopharm said that the appointments were part of the the initiation of its clinical trials program.

The company said that Prof de Souza was Western Sydney University's School of Medicine' foundation chair in medical oncology and would advise on both its clinical trial and drug development strategies and would chair the medical advisory panel. Noxopharm said that Prof de Souza had experience with its core technologies, having conducted the first phase Ib clinical study of idronoxil as well as a number of laboratory studies.

The company said that Prof Eade and Prof Hruby were staff members at Sydney's Royal North Shore Hospital and held clinical academic positions at the University of Sydney's Faculty of Medicine.

Noxopharm climbed six cents or 13.6 percent to 50 cents with 1.4 million shares traded.