



Biotech Daily

Wednesday December 6, 2017

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: VOLPARA UP 7%; DIMERIX DOWN 23%**
- * **NHMRC INCREASES FUNDING FOR WOMEN LEAD INVESTIGATORS**
- * **MELBOURNE BIOTECHS EGO, LEICA TAKE 2 OF 12 EXPORT AWARDS**
- * **PHARMAUST 'OVERSUBSCRIBED PLACEMENT' RAISES \$1.9m**
- * **DIMERIX 1-FOR-2 RIGHTS ISSUE FOR \$5.5m**
- * **GENERA, BECKMAN COULTER UNITE FOR DIAGNOSTICS**
- * **TEVA FILES APPLICATION FOR SUDA ZOLPIMIST FOR INSOMNIA**
- * **CLARITY LICENCES MELBOURNE UNI PROSTATE ANTIGEN IP**
- * **AUSCANN REQUESTS 'UPDATE' TRADING HALT**
- * **NOVITA REQUESTS 'GOVERNMENT GRANT' TRADING HALT**
- * **ZELDA TELLS ASX: 'MARIJUANA TRIAL REQUIRES COMPLEX APPROVAL'**
- * **REGAL TAKES 12% OF VISIONEERING**
- * **UWA PROF ELIZABETH RAKOCZY WINS \$50k CSL FLOREY MEDAL**

MARKET REPORT

The Australian stock market fell 0.44 percent on Wednesday December 6, 2017 with the ASX200 down 26.1 points to 5,945.7 points. Fourteen of the Biotech Daily Top 40 stocks were up, 17 fell, six traded unchanged and three were untraded.

Volpara was the best, up four cents or 6.8 percent to 63 cents with 31,709 shares traded. Genetic Signatures and Reva climbed more than six percent; Admedus was up 5.1 percent; Pharmaxis improved four percent; Clinuvel, Neuren and Starpharma were up more than three percent; Avita, Bionomics, ITL, Medical Developments, Mesoblast and Sirtex rose more than one percent; with Resmed up 0.9 percent.

Dimerix led the falls, down 3.5 cents or 22.6 percent to 12 cents with 588,889 shares traded. Airxpanders and Optiscan lost more than five percent; Actinogen and LBT fell four percent or more; Immutep (Prima) and Viralytics were down more than three percent; Benitec, Compumedics, CSL, Factor Therapeutics, Impedimed, Nanosonics, Osprey and Telix shed more than two percent; Orthocell was down 1.3 percent; with Cochlear, Ellex and Pro Medicus down by less than one percent.

[NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL \(NHMRC\)](#)

The National Health and Medical Research Council says it has increased funding for women researchers.

The NHMRC said that in 2017, 550 lead investigators shared \$471 million of funding, of which 152 were women.

The Council said the initiative would reduce the difference in funded rates between male and female lead investigators by providing an undisclosed amount to a further 34 female lead investigators, taking the total number of women lead investigators to 186.

The NHMRC said that the rate of successful funding through the Project Grants scheme had increased to 15.3 percent for women lead investigators, with the male funding rate remaining unchanged at 17.1 percent.

NHMRC chief executive officer Prof Anne Kelso said that “leading research provides an opportunity for women to contribute fully to the improvement of health and well-being through research and has a positive impact on their careers”.

[FEDERAL GOVERNMENT](#)

The Federal Government says Ego Pharmaceuticals has won the Australian exporter of the year award, with Leica Biosystems taking the health and biotechnology award. A media release from Austrade, the Federal Government-funded Australian Trade and Investment Commission, said that “12 national winners were selected from 77 finalists, who together generated \$3.9 billion in export earnings during 2016-'17 and employed 31,000 people”.

The media release said that last night’s 55th Australian Export Awards were hosted by the Federal Minister for Trade, Tourism and Investment Steven Ciobo in Canberra and Ego won both the top category as well as the manufacturing award.

The media release said that Ego was a family-owned dermatology pharmaceutical business, and researched, manufactured and marketed more than 120 products including QV Skincare, Sunsense sunscreen, Aqium Hand Sanitiser and Pinetarsol to 27 countries, with exports increasing 23 percent in the past year, comprising 43 percent of revenue.

The media release said that Leica won the health and biotechnology award for its cancer diagnostic instruments, with 90 percent of its products exported to 65 countries.

Austrade said that Leica was a leader in work-flow products “and the only company on the market providing instruments used from biopsy to diagnosis”.

The media release said that the Australian Export Awards were co-presented by Austrade and the Australian Chamber of Commerce and Industry.

For more information go to: www.exportawards.gov.au.

[PHARMAUST](#)

Pharmaust says it has raised \$1,873,000 through an “oversubscribed placement” to sophisticated investors and staff at 4.5 cents a share.

Pharmaust said that \$1,755,000 was placed to investors with officers of the company subscribing for \$118,000, subject to shareholder approval.

The company said the funds would accelerate development of monepantel for human and animal cancers and support strategic investment in its Epichem subsidiary.

Pharmaust chief executive officer Dr Richard Hopkins said the company was “delighted with the outcome to the placement”.

The company said that Argonaut Securities was the lead manager to the placement.

Pharmaust fell 0.3 cents or 6.1 percent to 4.6 cents with 1.5 million shares traded.

DIMERIX

Dimerix says it hopes to raise \$5,524,906 through a non-renounceable, one-for-two rights issue at 12 cents a share.

Dimerix said the funds would be used for DMX-200 for chronic kidney disease including the manufacture of the pharmaceutical ingredient and extended release tablet, regulatory activities, a phase II trial and a development plan for diabetic nephropathy.

The company said it had commitments from directors, management and existing shareholders for \$800,000 of the offer.

Dimerix said the record date would be December 11, the offer would open on December 13, 2017 and close on January 19, 2018.

Dimerix fell 3.5 cents or 22.6 percent to 12 cents.

GENERA BIOSYSTEMS

Genera says that it has a co-marketing partnership with Beckman Coulter Life Sciences.

Genera said the partnership would combine its Ampasand technology with Beckman Coulter's Cytoflex flow cytometry system, providing "high content flow cytometry, liquid handling automation and high multiplex [molecular diagnostics] testing".

Genera said the Australian-listed and CE-marked Paptype test detected and identified 14 high-risk types of human papilloma virus and two low-risk types in a single well.

The company said it had also commercialised RTIplex, which identified 15 common respiratory infections, including Influenza A and B, as well as 10 other viral and three bacterial disease-causing microbial targets.

Genera said it was developing a sexually transmitted infections panel that was expected to be available in early 2018.

Genera director Matthew Grigg said that "A key objective of pathology laboratories is to improve workflow and lab throughput capacity".

"This partnership will enable Genera's single-well Ampasand [molecular diagnostic] assays to meet the needs of pathology laboratories in Australia first and followed by an expansion into other countries," Mr Grigg said.

Genera chief executive officer Richard Hannebery told Biotech Daily that Beckman Coulter had an extensive list of contacts in the diagnostic industry and the two companies would present together in recommending Beckman Coulter's equipment and Genera's tests.

Genera fell 0.5 cents or 2.4 percent to 20 cents.

SUDA PHARMACEUTICALS

Suda says licensee, the Israel-based Teva Pharmaceuticals, has submitted its first marketing authorization application for Zolpimist for insomnia.

In July, Suda said the licence covered Brazil, Mexico and Chile, with an 18-month option to licence the product in Argentina, Israel and Australia (BD: Jul 5, 2017).

The company said the regulatory review would take up to 12 months.

Suda said that under the terms of the agreement, the approval of Zolpimist would trigger a payment.

Suda chief executive officer Stephen Carter said the company had worked with Teva to expedite the submission of the first marketing authorization application for Zolpimist.

"We are delighted that Teva has maintained its timetable of filing within five months from signing the licencing deal," Mr Carter said.

Suda fell 0.1 cents or 6.25 percent to 1.5 cents with 3.3 million shares traded.

CLARITY PHARMACEUTICALS

Clarity says it has licenced an Australian patent application for a prostate specific membrane antigen (PSMA) from the University of Melbourne.

Clarity said that the patent, entitled 'Copper based PSMA imaging agents' related to a targeting agent for imaging and treating prostate cancer and if granted would provide intellectual property protection until May 2037.

Clarity chief executive officer Dr Alan Taylor said that the company "already has nine patent families, five of which are for the core sarcophagine technology for cancer".

In November, Clarity said it had begun recruitment of a 10-patient phase I/IIa positron emission tomography imaging trial of copper-64 sartate to detect neuroblastoma at The company previously said that Sartate was copper-64 labelled octreotate, or ⁶⁴Cu Sartate, a positron emission tomography diagnostic used for the localization of somatostatin receptor-positive cancers such as neuroblastomas (BD: Aug 15, 2017).

Today, Clarity said the University of Melbourne's a prostate specific membrane antigen prostate cancer targeting agent had been developed over the last two years as part of a collaboration between Clarity, its scientific adviser and inventor of the underlying technology Prof Paul Donnelly at the University of Melbourne and the Peter MacCallum Cancer Centre's Prof Rodney Hick and his research team.

The company said that the PSMA was developed using the sarcophagine (SAR) technology which allowed for the potential for imaging and therapy.

Clarity said that prostate cancer was the most commonly diagnosed cancer in men and the world prostate cancer treatment market was predicted to reach \$US13.6 billion by 2021.

The company said that its technology had advantages over current technologies in development due to the benefits of using the radio-isotope pairing of copper-64 and copper-67, including centralized manufacture, diagnosis, prospective dosimetry and therapy.

Clarity said the methylated copper sarcophagine, or Mecosar, patent estate protecting its most advanced products had been granted in key jurisdictions including Australia, Canada, China, Japan, the US and Europe.

The company said that three other patent families, SAR-3, SAR-4, and SAR-5, covering radio-imaging and therapeutic agents had been filed, with SAR-3 granted in the US, Europe and Japan, SAR-4 granted in the US and Japan, SAR-5 granted in Europe and Japan, with applications for all three pending in other jurisdictions.

Clarity said that the patents and applications protect its lead product, Sartate for paediatric cancers, PSMA for prostate cancer and Bombesin, a pan cancer product which had shown effective and specific accumulation in pre-clinical cancer models and rapid clearance from the body, making it ideal for therapy and diagnostic development for a broad range of cancers including glioma, prostate, breast, small cell lung cancers, gastrointestinal stromal tumors and in-tumoral vessels of urinary cancers.

Clarity is a public unlisted company.

AUSCANN GROUP

Auscann has requested a trading halt "pending release of an announcement regarding an update on the Australian operations".

Trading will resume on December 8, 2017 or on an earlier announcement.

Auscann last traded at 68 cents.

[NOVITA HEALTHCARE \(FORMERLY AVEXA\)](#)

Novita has requested a trading halt pending an announcement regarding a ministerial announcement in respect of a significant research grant”.

Trading will resume on December 8, 2017 or on an earlier announcement.

Novita last traded at 4.5 cents.

[ZELDA THERAPEUTICS](#)

Zelda has told an ASX ‘aware’ query that the approval process for its medical marijuana trial for insomnia is complex, requiring approval from three parties.

Zelda said that clinical trials for schedule 8 drugs such as medicinal cannabis could not begin until it received approval from the human research ethics committee, the Australian Therapeutics Goods Administration and the Western Australian Department of Health.

The ASX aware query noted that the company responded to an earlier price and volume query, of a 30.0 percent rise from 9.0 cents to 11.7 cents on Tuesday November 21, saying that it did not have formal approvals to being the trial (BD: Nov 22, 2017).

The ASX said there was a further 34.8 percent increase in share price from 11.5 cents to 15.5 cents on Wednesday November 29, 2017.

Zelda said it was “inappropriate to make any announcement in relation to the receipt of approvals until all approvals, enabling the clinical trial to commence, have been received”.

Zelda said it first applied for ethics approval on April 26 and was granted initial approval from Bellberry on June 22, 2017

The company said TGA approval was granted on October 3 and it received approval from the Western Australian Department of Health on Friday, November 17, 2017.

Zelda said that any changes to the trial protocol meant that it had to return for further ethics approval and that was received from Bellberry on November 28, 2017.

Zelda was up 0.8 cents or 8.7 percent to 10 cents with 12.5 million shares traded.

[VISIONEERING TECHNOLOGIES](#)

Regal Funds says it has increased its substantial holding in Visioneering from 19,302,022 shares (9.80%) to 23,560,856 shares (11.96%).

The Sydney-based Regal Funds said that between June 14 and December 1, 2017 it bought 4,289,070 shares at prices between 34 and 40 cents a share.

The company said that it sold 30,236 shares on September 15, 2017 at 40 cents a share.

Regal said that the registered holders of the securities were UBS Nominees Pty Ltd, Credit Suisse Securities Europe Ltd and Merrill Lynch Australia Nominees Pty Ltd.

Visioneering fell 0.5 cents or 1.25 percent to 39.5 cents.

[CSL](#)

CSL says that University of Western Australia Prof Elizabeth Rakoczy has won the \$50,000 CSL Florey medal for lifetime achievement for work in the restoration of sight.

CSL said that Prof Rakoczy was the founding director of the University’s Department of Molecular Ophthalmology at the Lions Eye Institute and had developed a gene therapy to modify a virus to carry a gene into eye cells, replacing the need for injections.