

Biotech Daily

Tuesday July 16, 2019

Daily news on ASX-listed biotechnology companies

- * ASX DOWN, BIOTECH EVEN: RESONANCE UP 19%; ALTERITY (PRANA) DOWN 10%
- * BIOCURATE, SERVIER TO ACCELERATE DRUG DISCOVERY
- * CLARIFICATION: VICTORIA GOVERNMENT, JOHNSON & JOHNSON INNOVATION
- * STARPHARMA RECEIPTS UP 1% TO \$2.8m, \$51m CASH
- * IMMURON REVENUE UP 29% TO \$2.6m, 1st US \$1m TRAVELAN SALES
- * UNIVERSAL BIOSENSORS SIEMENS STRIPS UP 156% TO \$2.3m, \$51m CASH
- * FDA APPROVES AIRXPANDERS AEROFOAM; DIRECTOR ZETA PEACH RESIGNS
- * ADALTA STARTS AD-214 FOR IPF TOXICOLOGY STUDY
- * ALCIDION TO SUPPLY SCRIPT SYSTEM FOR DARTFORD, GRAVESHAM NHS
- * OVENTUS 'LAB-IN LAB' AGREEMENTS WITH 3 US COMPANIES
- * STEMCELL UNITED, MALAYA UNI RESEARCH AGREEMENT
- * NEUREN RECEIVES FINAL PAYMENT FROM LANSTEAD; TOTAL \$12m
- * NUHEARA'S TIM ROBERTSON, FARJOY INCREASE, DILUTED TO 10%
- * M&G IN AND OUT OF MEDICAL DEVELOPMENTS
- * DEUTSCHE BANK BELOW 5% IN GENETIC SIGNATURES
- * BARD1 DIRECTOR DR IRMGARD IRMINGER-FINGER INCREASES, DILUTED TO 8%
- * CEO MIRIAM HALPERIN INCREASES, DILUTED TO 8.5% OF CRESO
- * CHAIR BOAZ WACHTEL INCREASES, DILUTED TO 5.5% OF CRESO
- * ELIXINOL: STRATOS KAROUSOS CEO ON \$338k, PAUL BENHAIM CIO
- * NOXOPHARM: DR NIECHODA DIRECTOR, NYRADA BOARD CHANGES

MARKET REPORT

The Australian stock market fell 0.18 percent on Tuesday July 16, 2019, with the ASX200 down 12.0 points to 6,641.0 points. Fifteen of the Biotech Daily Top 40 stocks were up, 14 fell, seven traded unchanged and four were untraded.

Resonance was the best, up two cents or 19.05 percent to 12.5 cents with 4.3 million shares traded. Actinogen and Cynata climbed more than 11 percent; Imugene was up 6.7 percent; Prescient improved 5.3 percent; Genetic Signatures, LBT and Mesoblast were up more than four percent; Oncosil, Optiscan and Starpharma rose three percent or more; Avita, Clinuvel and Osprey were up more than one percent; with Cochlear, CSL and Paradigm up by less than one percent.

Alterity (Prana) led the falls, down 0.3 cents or 10 percent to 2.7 cents, with 42,000 shares traded. Impedimed lost 7.4 percent; Orthocell fell 5.5 percent; Kazia, Polynovo and Pro Medicus were down more than three percent; Volpara shed 2.35 percent; Benitec, Compumedics, Cyclopharm, Medical Developments, Neuren and Proteomics were down one percent or more; with Nanosonics and Resmed down by less than one percent.

BIOCURATE

Biocurate says it will collaborate with Servier Australia to share commercial and scientific expertise to accelerate the discovery of new therapeutics and drugs.

Biocurate said it would work directly with the subsidiary of the Paris-based Servier Group and through Biocurate's industry and scientific advisory committee, in providing advice and assessing new therapeutic candidates from Biocurate's academic partners.

The organization said it was formed from a collaboration between the University of Melbourne and Monash University with support from the Victoria Government and to address barriers "that limit the translation and commercialization of early stage research". Biocurate chief executive officer Dr Glenn Begley said the organization was "very pleased

... to be expanding our collaborative linkages with experts who are able to provide invaluable scientific advice, commercial insight and partnering opportunities".

"Our staff are solely focused on increasing the clinical impact from medical research and we are doing this by sharing our hands-on experience, knowledge and networks from working in industry both internationally and in Australia," Dr Begley said.

The company said that Servier International Center of Therapeutic Research had "actively engaged some of the best researchers worldwide" to capture the opportunities of research and development ecosystems, such as Australia, and to further strengthen its pipeline. Servier head of research and development Claude Bertrand said that "collaboration with biotech companies, academia, institutes and government is a key cornerstone of our strategy to put the patient and innovation first".

Biocurate said the collaboration would create synergies between Servier's scientific expertise and capabilities and Biocurate's know-how in improving the quality of early stage research for translation into therapeutic products.

VICTORIA GOVERNMENT JOHNSON & JOHNSON INNOVATION

Last night's edition reported initiatives taken by the Victoria Government including "a collaboration with Johnson & Johnson to support innovation at Monash University". In fact, Johnson & Johnson Innovation says it supports "entrepreneurs, academics, biotechnology companies, investors and incubators across Australia through mentoring, training and networking events".

"In Victoria, this is done through the Johnson & Johnson Innovation Partnering Office at Monash University (JJIPO@Monash) with the goal to identify early-stage research and biotechnology and medical technology opportunities for collaboration and investment," Johnson & Johnson Innovation said.

No sub-editors have been hurt in making this clarification.

STARPHARMA

Starpharma says that receipts from customers for the year to June 30, 2019 was up 0.7 percent to \$2,807,000.

Starpharma told Biotech Daily that the receipts included a \$2.0 million milestone on signing the Mundipharma Vivagel BV for bacterial vaginosis Europe deal last year as well as \$800,000 from product supply, royalties and research revenue from partners, the majority being Vivagel related including Vivagel BV and Vivagel condoms.

The company's Appendix 4C said that the cash burn for the three months to June 30 was \$2,695,000, the company had cash at June 30 of \$51,319,000 with an expected cash outflow of the three months to September 30, 2019 of \$5,100,000.

Starpharma was up four cents or three percent to \$1.38.

<u>IMMURON</u>

Immuron says that revenue for the year to June 30, 2019 was up 29 percent to \$2.6 million with North America Travelan for diarrhoea up 52 percent to \$1.16 million. Immuron said that US Travelan sales were more than \$1 million for the first time, with sales increasing 32 percent over the previous corresponding period.

Immuron chief executive officer Dr Gary Jacob said that the company "added to the ongoing successful efforts in Australia by working hard to increase awareness of Travelan amongst North American consumers, using podcasts and collaborations with travel bloggers to educate and inform the market regarding the virtues of our product".

"The new 2020 fiscal year will see our efforts ramp-up even further in North America as we expand distribution channels and work to further consumer demand in that very important geographic area using pull-through marketing campaigns and other forms of advertising," Dr Jacob said.

Immuron was up three cents or 26.1 percent to 14.5 cents with 1.5 million shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says that revenue from the supply of test strips to Siemens Healthcare for the six months to June 30, 2019 was up 155.5 percent to \$2.3 million. Universal Biosensors interim chief executive officer Salesh Balak told Biotech Daily the supply of the Xprecia Stride PT-INR test strips was the company's main continuing revenue along with \$1.5 million from Canada subsidiary HRL for coagulation testing. In February, the company said it had received \$US31,503,880 (\$A44,036,123) as a lump sum service fee from Johnson & Johnson's Lifescan as a buy-out from Lifescan's obligation to pay quarterly service fees for its Verio blood sugar test strips and it would not receive any further quarterly services fees (BD: Sep 26, 2018; Feb 18, 2019). Today the company said that total receipts from customers amounted to \$52,139,000, it had a cash burn of \$1,860,000 for the three months to June 30, cash of \$50,890,000 at June 30 and expected cash outflows for the three months to September 30 of \$3,223,000. Universal Biosensors was unchanged at 25 cents.

AIRXPANDERS

Airxpanders says it has US Food and Drug Administration 510(k) clearance for its smooth shell Aerofoam breast tissue expander, and director Zita Peach has resigned. Last week, Airxpanders said that due to lymphoma fears, the Australian Therapeutic Goods Administration had proposed a six-month sales and distribution suspension of Aerofoam, but had not decided not to suspend the device (BD: Jul 10, 2019). The company said at that time that the suspension proposal was the result of a TGA review of all textured breast implants in relation to breast implant associated anaplastic large cell lymphoma and there had been no incidents reported to date involving the Aeroform breast expander system (BD: Jul 10, 2019).

Today, Airxpanders chief executive officer Frank Grillo said "the plastic surgery community has embraced the textured version of our tissue expander, and they have also been asking us to provide a smooth, untextured version of Aeroform".

"This clearance enables market release in the US, and we have already submitted our regulatory application for [Conformité Européene] mark approval," Mr Grillo said. Separately, the company said director Zita Peach had resigned from the board. Airxpanders gave no further information and did not mention a replacement.

Airxpanders was in an extended suspension and last traded at 3.5 cents.

ADALTA

Adalta says it has begun a four-week, non-human primate safety and toxicology study of AD-214 for idiopathic pulmonary fibrosis.

Adalta said the study data was expected by the end of 2019 and would inform the dosing and safety readouts for a phase I, human clinical trial expected to begin in January 2020. The company said the results would also form part of a subsequent investigational new drug submission to the US Food and Drug Administration.

Adalta chief executive officer Sam Cobb said "we have met all our manufacturing objectives for our lead candidate AD-214".

"Manufacturing is a key step in making any product and is particularly difficult with new biologic drugs," Mr Cobb said. "We now have the materials to commence our four-week toxicology study, which will evaluate the safety of AD-214."

In May, Adalta said it had completed a confirmation run for manufacturing of AD-214 which showed a cell-line expression at a 50-litre scale and purification, combined into a single manufacturing process (BD: May 2, 2019).

Adalta was up half a cent or 3.1 percent to 16.5 cents.

<u>ALCIDION</u>

Alcidion says it expects to supply the UK's Dartford and Gravesham National Health Service Trust's electronic prescription medications administration system.

Alcidion said that under "preferred provider" status, it would deploy Better by Marand's 'Openep' platform for electronic medication management, to prevent adverse medicationrelated events, subject to final approval of a contract, expected in late 2019.

Alcidion managing-director Kate Quirke said the "selection of Alcidion demonstrates the breadth of our capabilities and our value as the trust's strategic partner to support its goal of being 'Paperless at the Point of Care by 2020'".

"This is the first major tender for which Alcidion has been selected to supply the Openep platform," Ms Quirke said.

Alcidion was up half a cent or 3.1 percent to 16.5 cents with 3.7 million shares traded.

OVENTUS MEDICAL

Oventus says it has agreements with US companies Virtuox, Carestream Dental and Lyon Dental for its laboratory inside a laboratory, or lab-in-lab business model.

Last month, Oventus chief executive officer Dr Chris Hart told Biotech Daily that the laboratory inside a laboratory "uses a scanner to measure the patient's mouth size for a custom-fit for the O2Vent" for sleep apnoea (BD: Jun 24, 2019).

The company said the agreement with the Rochester, New York-based Carestream Dental would supply affordable scanning technology to sleep facilities and expand the customer base in North America to potential patients with obstructive sleep apnoea. Oventus said the agreement with Coral Springs, Florida–based Virtuox, a respiratory testing provider, would allow "management of the patients' sleep apnoea under the clinical management of sleep physicians".

The company said the agreement with the Novi, Michigan-based Lyon Dental would ensure that patients could access reimbursement for Oventus technology.

Dr Hart said that "by bringing together the backbone of Virtuox, Carestream Dental and Lyon Dental, we have created a solution whereby dentists and sleep networks can provide patients with end-to-end support for their obstructive sleep apnoea".

Oventus was up nine cents or 29.0 percent to 40 cents.

STEMCELL UNITED

Stemcell United says it has an agreement with the University of Malaya for medicinal plant research.

Stemcell said both parties would share knowledge and expertise though joint research and the exchange of academic materials.

Stemcell chief executive officer Philip Gu said the collaboration would advance [the company's] traditional medicine research in plants such as hemp, dendrobium officinal and Daemonorops draco blume" or dragon's blood (BD: May 18,2017). Stemcell United was unchanged at 1.5 cents.

NEUREN PHARMACEUTICALS

Neuren says it has received the final payment from Lanstead Capital's "sharing agreement" taking the total received to \$12.2 million.

Neuren said the original commitment was for \$10 million, be paid in 18 monthly settlements measured against a benchmark price of the then 8.86 cents a share, and \$1.772 following a 20-to-one consolidation (BD: Jun 29, Nov 17, 2017).

In 2017, the company said that if the share price exceeded the benchmark for the month, Neuren would receive more than 100 percent of the settlement on a pro-rata basis, with no upper limit, but if the share price fall below 8.86 cents and later, \$1.772, the company would receive less than 100 percent of the settlement on a pro-rata basis.

In 2018, Neuren said Lanstead agreed to pause the monthly settlements for 120 days, when it was trading at \$1.14, saying that given its "strong cash positions, Lanstead settlements [were] not required to fund [its] expenditure in the short term ... [and] the current share price [did] not fairly represent the underlying value of the business", so it was in Neuren's best interests to defer the remaining settlements (BD: Aug 29, 2018). Neuren fell two cents or 1.4 percent to \$1.43.

NUHEARA

The Sydney-based Farjoy says it has increased and been diluted in Nuheara from 70,407,585 shares (7.90%) to 108,740,919 shares (10.24%).

A substantial shareholder notice signed by Farjoy managing-director and Nuheara director Tim Robertson, said that through placements on December 10, 2018 it had acquired 13,333,334 shares for \$1,000,000 or 7.5 cents a share and on July 15, 2019 had acquired 25,000,000 shares for \$1,250,000 or five cents a share.

Nuheara was up 0.3 cents or 6.1 percent to 5.2 cents with 6.3 million shares traded.

MEDICAL DEVELOPMENTS INTERNATIONAL

The London-based M&G Investment Funds says it became and ceased to be a substantial shareholder in Medical Developments on July 12, 2019.

M&G said it had acquired 3,295,094 shares or 5.02 percent of Medical Developments through an "in-specie transfer" for \$18,913,840 or \$5.74 a share.

In a separate notice, the company said it had ceased its substantial holding on July 12, through an in-specie transfer out of 3,276,990 shares for \$18,809,923 or \$5.74 a share. Medical Developments fell six cents or one percent to \$6.10 with 285,090 shares traded.

GENETIC SIGNATURES

The Frankfurt, Germany-based Deutsche Bank AG says it has ceased its substantial holding in Genetic Signatures.

In a substantial shareholder notice, Deutsche Bank said that between December 18, 2018 and July 4, 2019 it bought and sold shares at prices ranging from 71 cents to \$1.25 each, with a single largest sale 13,500 shares for \$10,935 or 81 cents a share. Genetic Signatures was up five cents or 4.55 percent to \$1.15.

BARD1 LIFESCIENCES

Bard1 director Dr Irmgard Irminger-Finger says she has increased but been diluted from 112,152,737 shares (11.28%) to 112,652,737 shares (8.24%).

Dr Irminger-Finger said between November 27 and 29, 2018 she sold 8,599,683 shares for \$204,982 or an average of 2.38 cents a share.

The substantial shareholder notice said that through a rights issues on December 17, 2018 Dr Irminger-Finger acquired 12,500,000 shares for \$250,000 or a 2.0 cents a share and through a rights issue on July 12, 2019 acquired 500,000 shares for \$10,000 or 2.0 cents a share.

Bard1 was up 0.1 cents or 3.7 percent to 2.8 cents with 5.4 million shares traded.

CRESO PHARMA

Creso chief executive officer Miriam Halperin Wernli says she has increased her holding but been diluted from 8,250,000 shares (10.17%) to 12,800,000 shares (8.84%). Ms Halperin Wernli along with Jorge Wernli said that between July 27, 2018 and July 2, 2019 they acquired 4,550,000 shares through the vesting of performance rights. Creso fell half a cent or 1.15 percent to 43 cents.

CRESO PHARMA

Creso chairman Boaz Wachtel says he has increased in Creso from 6,800,000 shares to 8,300,000 shares but been diluted from 8.39 percent to 5.50 percent. Mr Wachtel says that through the Kfar Neter, Israel-based International Water Energy Savers on July 2, 2019 he acquired 1,500,000 shares from the vesting of performance rights.

ELIXINOL GLOBAL

Elixinol says it has appointed Stratos Karousos as chief executive officer effective immediately, replacing Paul Benhaim who continues as chief innovation officer. Elixinol said that Mr Karousos would re-join Mr Benhaim as a director. The company said Mr Karousos would have a base salary of \$337,500 including superannuation, with short term incentives of up to 25 percent of his total fixed remuneration and long-term incentives of performance share rights. Elixinol fell 10 cents or 2.4 percent to \$4.00 with 402,717 shares traded.

NOXOPHARM

Noxopharm says it has appointed Dr Beata Niechoda as a director, and appointed John Moore as subsidiary Nyrada executive chair with two new directors.

Noxopharm said Dr Niechoda previously held executive positions at Shire Australia, Eli Lilly Australia and New Zealand, and Amgen Australia and New Zealand.

The company said Dr Niechoda held a Doctor of Medicine from Medical University Gdansk, Poland, a Doctor of Philosophy and a Master of Business Administration from the University of New South Wales.

Noxopharm said John Moore was previously a Noxopharm director and prepared Nyrada for a public listing.

The company said it had appointed Marcus Frampton and Dr Rüdiger Weseloh as Nyrada directors.

Noxopharm said Mr Frampton was currently Alaska Permanent Fund Corp chief investment officer and held a Bachelor of Business-Economics from the University of California, Los Angeles.

The company said Mr Weseloh was currently a business development director at the Darmstadt, Germany-based Merck KGaA and held a Doctor of Philosophy from Hamburg's Centre for Molecular Neurobiology.

Noxopharm fell 2.5 cents or 5.6 percent to 42.5 cents.