

Biotech Daily

Thursday February 28, 2019

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH UP: IMUGENE UP 18%; OPTISCAN DOWN 10%
- * ZELDA: 'ENDO-CANNABINOID HER2 BREAST CANCER PATH'
- * TPI REVENUE UP 109% TO \$47m, LOSS DOWN 65% TO \$6m
- * NEUREN REVENUE UP 49% TO \$15.2m, PROFIT DOWN 7% TO \$3.1m
- * AIRXPANDERS REVENUE UP 100% TO \$11m, LOSS DOWN 8% TO \$37m
- * AVITA H1 REVENUE UP 53% TO \$6.8m, LOSS UP 115% TO \$15.6m
- * IQ3 H1 REVENUE DOWN 15% TO \$2.9m, PROFIT UP 333% TO \$320k
- * USCOM H1 REVENUE UP 4% TO \$1.5m, LOSS DOWN 30% TO \$758k
- * PHOSPHAGENICS REVENUE UP 21% TO \$1.4m, LOSS DOWN 53% TO \$4m
- * ADHERIUM H1 REVENUE DOWN 63% TO \$986k, LOSS UP 74% TO \$8.6m
- * TOTAL BRAIN H1 REVENUE UP 4% TO \$1.1m, LOSS DOWN 62% TO \$4.6m
- * MICRO-X QUITS XINRAY
- * ADALTA, EXCELLERATE COLLABORATE ON I-BODY
- * REGENEUS \$2.5m DIRECTORS LOANS
- * HARBOUR TAKES 5% OF VOLPARA, AGAIN
- * SIMON HARRADENCE, DDH GRAHAM, LUGARNO TAKE 6% OF ACRUX
- * SPILL CALL SHAREHOLDERS TAKE 18% OF FACTOR
- * PYXIS TAKES 6% OF NEUROTECH
- * DUNCAN CORNISH REPLACES ANTEO CFO, CO SEC JULIEN MCINALLY

MARKET REPORT

The Australian stock market was up 0.3 percent on Thursday February 28, 2019, with the ASX200 up 18.7 points to 6,169.0 points. Twenty of the Biotech Daily Top 40 stocks were up, 15 fell, three traded unchanged and two were untraded. All three Big Caps were up.

Imugene was the best on news in a month, up 0.3 cents or 17.65 percent to two cents, with 26.9 million shares traded. Patrys climbed 9.5 percent; Cyclopharm and Polynovo were up more than five percent; Universal Biosensors and Uscom rose more than four percent; Clinuvel, CSL, Immutep, Kazia, Resmed and Starpharma were up more than three percent; Airxpanders, Oncosil, Pro Medicus and Volpara rose more than two percent; with Actinogen, Cynata, Dimerix, Paradigm, Prescient and Telix up more than one percent.

Optiscan led the falls, down 0.6 cents or 10.3 percent to 5.2 cents with 269,576 shares traded. Ellex and LBT lost more than six percent; Neuren, Osprey and Proteomics fell more than four percent; Avita and Orthocell, were down more than three percent; Genetic Signatures shed 2.15 percent; with Compumedics, Medical Developments, Mesoblast, Nanosonics, Opthea and Pharmaxis down by more than one percent.

ZELDA THERAPEUTICS

Zelda says that a study by one of its advisors Prof Cristina Sanchez "identified a new target in the endo-cannabinoid system for treatment of HER2+ breast cancer".

The article, titled 'Therapeutic targeting of HER2–CB2R heteromers in HER2-positive breast cancer' was published by the US Proceedings of the National Academy of Sciences and an abstract is at https://www.pnas.org/content/116/9/3863.abstract.

Zelda said that working with her team at the Madrid, Spain-based Complutense University, the study described a mechanism by which the cannabinoid receptor CB2 bound the HER2 receptor to form a novel complex.

The company said that HER2 was a biomarker for aggressive cancer and was found in about 20 percent of breast cancer patients.

Zelda said the study showed that expression of HER2-CB2R receptor complexes correlated with poor prognosis in breast cancer patients.

The company said that treatment with delta-9-tetrahydrocannbinol, or THC, bound to the CB2 receptor, disrupted HER2-CB2R heteromers and promoted anti-tumor responses, in both in-vitro experiments and in mice.

The abstract for the published article said the significance of the work was that "Here, we show that HER2 forms heteromer complexes with the cannabinoid receptor CB2R, the expression of these structures correlates with poor patient prognosis, and their disruption promotes anti-tumor responses."

"Collectively, our results support HER2–CB2R heteromers as new therapeutic targets and prognostic tools in HER2+ breast cancer, the research study said.

"Here, we unveil a mechanism controlling the oncogenic activity of HER2:

heteromerization with the cannabinoid receptor CB2R," the researchers said.

"We show that HER2 physically interacts with CB2R in breast cancer cells, and that the expression of these heteromers correlates with poor patient prognosis," the article said.

"The cannabinoid delta-9-tetrahydrocannabinol disrupts HER2–CB2R complexes by selectively binding to CB2R, which leads to (i) the inactivation of HER2 through disruption of HER2–HER2 homodimers, and (ii) the subsequent degradation of HER2 by the proteasome via the E3 ligase c-CBL," the researchers said.

"This in turn triggers anti-tumor responses in-vitro and in-vivo," the article said. "Selective targeting of CB2R transmembrane region 5 mimicked THC effects," the stud said.

"Together, these findings define HER2–CB2R heteromers as new potential targets for antitumor therapies and biomarkers with prognostic value in HER2-positive breast cancer," the article said.

Zelda chief executive officer Dr Richard Hopkins said the paper "makes an important contribution to our understanding of the role of the endocannabinoid system in cancer and has identified a novel therapeutic target for management of HER2+ breast cancer".

Dr Hopkins told Biotech Daily that the research identified a disruption of a cancer pathway and although that was achieved by the marijuana-derived THC the end product drug may well be a completely different molecule designed to bind to the identified receptors.

"This study provides further validation of Zelda's strategy to partner with the world's leading researchers and represents an important step towards development of new cannabis-based therapies for treatment of cancer," Dr Hopkins said.

The company said its pre-clinical cancer research was "designed to build a ... data set and ... intellectual property in a form that can be licenced to third parties".

Zelda said that under the agreement with Prof Sanchez and Complutense University, intellectual property generated from the collaboration would be assigned to Zelda. Zelda was up 0.4 cents or 7.55 percent to 5.7 cents with 1.6 million shares traded.

TPI (TASMANIAN POPPY INDUSTRIES) ENTERPRISES

TPI says revenue for the 12 months to December 31, 2018 was up 109.1 percent to \$46,563,381 with net loss after tax down 65.3 percent to \$5,788,409.

TPI said revenue came from the sales of poppy seed, narcotic raw material and active pharmaceutical ingredient.

The company said diluted loss per share was down 63.3 percent to 8.52 cents, net tangible assets per share was constant at 43 cents at December 31, 2018, and it had cash and cash equivalents of \$1,904,583 at December 31, 2018 compared to \$3,644,547 at December 31, 2017.

TPI was up six cents or 6.5 percent to 98 cents with 1.2 million shares traded.

NEUREN PHARMACEUTICALS

Neuren says revenue for the 12 months to December 31, 2018 was up 49.3 percent to \$15,169,000 with net profit after tax down 6.5 percent to \$3,073,000.

Neuren said the increase in revenue was primarily due to its licence agreement with Acadia Pharmaceuticals for trofinetide in North America (BD: Aug 7, 2018).

The company said diluted earnings per share was down 11.4 percent to 3.1 cents, net tangible assets was up 50 percent from 16 cents to 24 cents at December 31, 2018, and it had cash and cash equivalents of \$23,576,000 at December 31, 2018 compared to \$4,706,000 at December 31, 2017.

Neuren fell 5.5 cents or 4.6 percent to \$1.14.

AIRXPANDERS

Airxpanders says revenue for the year to December 31, 2018 was up 100.1 percent to \$US7,817,000 (\$A10,942,784) with net loss after tax down 7.8 percent to \$US26,721,000 (\$A37,405,926).

Airxpanders said revenue came from sales of its Aeroform post-mastectomy breast tissue expander system.

The company said diluted loss per US share was down 32.3 percent to 21 US cents, net tangible assets per US share was down from 17 US cents to 2.0 US cents per US share or from 6 US cents per Australian Chess depository instruments (CDIs) to 0.8 US cents per CDI at December 31, 2018, and it had cash and cash equivalents of \$US9,375,000 at December 31, 2018 compared to \$US4,162,000 at December 31, 2017.

Airxpanders was unchanged at 3.8 cents.

AVITA MEDICAL

Avita says revenue for the six months to December 31, 2018 was up 52.8 percent to \$6,822,000, with net loss up 114.9 percent to \$15,579,391.

Avita said revenue from sales of its Recell system for the treatment of burns was up 198.3 percent to \$1,813,195, with first US sales of \$1,102,000 for the six months.

The company said other revenue included funding from the Biomedical Advanced Research and Development Authority (BARDA) of \$5,009,137, up 29.9 from the previous corresponding period.

Avita said diluted loss per share was up 74.7 percent to 1.59 cents, net tangible assets per share rose from 1.38 cents to 1.89 cents, with cash and equivalents of \$30,342,360 at December 31, 2018 compared to \$11,777,009 at December 31, 2017.

Avita fell half a cent or 3.6 percent to 13.5 cents with 4.0 million shares traded.

IQ3 CORP

IQ3 says revenue for the six months to December 31, 2018 was down 14.9 percent to \$2,925,265 with net profit after tax up 333.4 percent to \$320,357.

IQ3 said revenue came from the "provision of capital raising and corporate advisory services to listed and unlisted companies in the life sciences industry".

The company said diluted earnings per share was up 342.9 percent to 0.31 cents, net tangible assets per share was up from 1.68 cents to 1.96 cents, and it had cash and equivalents of \$190,243 at December 31, 2018 compared to \$377,985 the prior year. IQ3 was untraded at 29 cents.

USCOM

Uscom says revenue for the six months to December 31, 2018 was up 4.4 percent to \$1,485,823 with net loss after tax down 30.1 percent to \$757,972.

Uscom said revenue was up largely due to increased Chinese and European purchases of its Uscom1a ultra-sonic cardiac output monitors and would be enhanced by US Food and Drug Administration approvals for its BP+ blood pressure monitor and Spirosonic respiratory monitor devices.

The company said diluted earnings per share was down 44.4 percent to 0.5 cents, net tangible assets was down from 3.3 cents to 2.2 cents at December 31, 2018, and it had cash and cash equivalents of \$2,182,670 at December 31, 2018 compared to \$3,487,644 at December 31, 2017.

Uscom was up half a cent or 4.2 percent to 12.5 cents.

PHOSPHAGENICS

Phosphagenics says revenue for the year to December 31, 2018 was up 21.2 percent to \$1,394,275 with net loss after tax down 53.3 percent to \$3,991,020.

Phosphagenics said revenue came primarily from the sales of its Vital ET, vitamin E cream derivative to Ashland Industries Europe.

The company said diluted loss per share was down 62.1 percent to 0.25 cents, net tangible assets was fell from 0.28 cents to 0.16 cents at December 31, 2018, and it had cash and cash equivalents of \$2,111,171 at December 31, 2018 compared to \$2,898,596 at December 31, 2017.

Phosphagenics was unchanged at 0.4 cents with 3.2 million shares traded.

ADHERIUM

Adherium says revenue for the six months to December 31, 2018 was down 62.9 percent to \$986,000 with net loss after tax up 73.7 percent to \$8,647,000.

Adherium said the fall in revenue "was due to a significant level of innovative product design and engineering services ...undertaken in the prior year".

The company said "there was a halt in production of one of [its] sensors at its contract manufacturer at the end of the September quarter to implement a design change", with production resuming by the end of 2018, and the production backlog to be cleared by today, with related revenue and receipts from customers to be reported by July 2019. Adherium said diluted loss per share was up 72.4 percent to 5.0 cents, net tangible assets per share fell 77.7 percent to 2.2 cents, and it had cash and cash equivalents of \$4,093,000 at December 31, 2018 compared to \$14,935,000 at December 31, 2017. Adherium was up 0.4 cents or 15.4 percent to three cents.

TOTAL BRAIN

Total Brain says revenue for the six months to December 31, 2018 was up 4.3 percent to \$1,104,871 with net loss after tax down 62.3 percent to \$4,566,467.

Total Brain said revenue was from its brain training devices.

The company said diluted loss per share was down 99.8 percent to 0.01 cents and had cash and cash equivalents of \$3,267,817 at December 31, 2018 compared to \$8,760,657 at December 31, 2017.

Total Brain was untraded at 2.6 cents.

MICRO-X

Micro-x says it has sold its 30 percent holding in Xinray Systems in a buy-back of shares it acquired in January 2016.

In 2017, Micro-X took control of x-ray tube production from Xinray (BD: Aug, 17, 2017. Today, the company said proceeds exceeding its investment in Xinray would be used as credit against invoices for the supply of x-ray tubes.

Micro-X was unchanged at 27 cents.

ADALTA

Adalta says it will collaborate with the Nottingham, UK-based Excellerate Bioscience to develop its i-body pipeline.

Adalta said the collaboration would identify i-bodies, named from the "intermediate" of four groups of immunoglobulin or immunoglobulin-like domains, with efficacy, safety and duration and determine which ones were best-in-class for binding to drug targets, specifically G protein-coupled receptors".

The company said it would screen its i-body library and Excellerate would profile and assess for drug candidates, and G protein-coupled receptors were involved in diseases including obesity and diabetes but many were "difficult to target by small molecule and traditional antibody therapeutics".

Adalta was up one cent or 4.2 percent to 25 cents.

REGENEUS

Regeneus says it has a 12-month, \$2.5 million loan from directors for the development and licencing of its clinical assets.

Regeneus said the loan would be on "an arms-length basis" and would assist it to licence its Progenza stem cell technology.

Regeneus was up half a cent or 4.8 percent to 11 cents.

VOLPARA HEALTH TECHNOLOGIES

Harbour Asset Management says it has become a substantial shareholder in Volpara with 9,025,027 shares or 5.032 percent of the company.

The Wellington, New Zealand-based Harbour said it acquired the shares between November 28, 2018 and February 27, 2019, with the single largest purchase 223,724 shares for \$237,461 or \$1.06 a share.

Harbour previously became substantial in Volpara in October 2018 and fell below five percent in November 2018 (BD: Oct 9, Nov 9, 2018).

Volpara was up three cents or 2.9 percent to \$1.075.

ACRUX

Brisbane's Simon Harradence, DDH Graham and the Lugarno Fund say they have become substantial shareholders in Acrux with 9,895,863 shares of 5.94 percent. A substantial shareholder notice, signed by director Simon Harradence on behalf Lugarno Partners, DDH Graham as trustee for the Lugarno Fund, the AVSH Trust and One Blind Mouse SF, said the group acquired the shares on and off market between December 12, 2018 and February 15, 2019 with the single largest purchase 9,767,196 shares for \$1,758,095 or 18.0 cents a share.

Acrux was unchanged at 16.5 cents.

FACTOR THERAPEUTICS

The shareholders calling for a board spill say they have increased their shareholding in Factor from 155,078,379 shares (14.87%) to 190,617,214 shares (18.28%) Earlier this month, the shareholders requested a board spill to replace chair Dr Cherrell Hirst and directors Tim Hughes and John Michailidis with Bruce Lane and David Sanders, with the meeting due to be held on March 29, 2019 (BD: Feb 5, Feb 22, 2019). Today's substantial shareholder notice said Pura Vida Energy NL acquired 35,538,835 shares on February 26, 2019 for \$137,681.44, or 3.87 cents a share. Factor fell 0.1 cents or 20 percent to 0.4 cents.

NEUROTECH INTERNATIONAL

The Perth-based Pyxis Holdings says it has become a substantial shareholder in Neurotech with 7,499,999 shares or 5.53 percent of the company.

A substantial shareholder notice signed by director C K Teo said Pyxis for the Mapletree account acquired the shares in rights issue at three cents a share which raised \$783,689 of a hoped-for \$3.3 million (BD: Jan 29, Feb 25, 2019).

Neurotech fell 0.2 cents or 7.1 percent 2.6 cents.

ANTEO DIAGNOSTICS

Anteo says it has appointed Duncan Cornish as chief financial officer and company secretary, replacing Julien McInally.

Anteo said Mr Cornish previously worked in England and Australia at accountancy firms Ernst & Young and Pricewaterhousecoopers.

The company said he had worked as a chief financial officer and company secretary for Australian and Canadian public companies.

Anteo was unchanged at 1.9 cents with 5.1 million shares traded.