

Biotech Daily

Wednesday February 7, 2018

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH UP: USCOM UP 15%; GENETIC SIGNATURES DOWN 12%
- * ALLERGAN BUYS ELASTAGEN FOR \$120m
- * IMUGENE IMU-131 VACCINE 'SHOWS PROMISE FOR GASTRIC CANCER'
- * WEHI: CONTROL NOD2 IMMUNE RESPONSE FOR INFLAMMATION
- * AVIRAGEN (BIOTA) DELAYS VAXART MERGER EGM 3 DAYS
- * MMJ HOPES FOR 70 TONNES OF CANNABIS FLOWER BY 2020
- * HYDROPONICS TO OPEN MARIJUANA CLINICS BY JULY
- * RHYTHM DEVELOPS REAGENTS FOR COLOSTAT CANCER TEST
- * TRIBECA TAKES 5% OF CANN
- * NAOS TAKES 16% OF BIOTECH CAPITAL

MARKET REPORT

The Australian stock market rose 0.75 percent on Wednesday February 7, 2018 with the ASX200 up 43.5 points to 5,876.8 points. Twenty-seven Biotech Daily Top 40 stocks were up, seven fell, five traded unchanged and one was untraded. All three Big Caps were up.

Uscom was the best, up three cents or 15 percent to 23 cents with 203,226 shares traded.

Volpara climbed 14.9 percent; Actinogen was up 11.9 percent; Airxpanders improved 9.1 percent; Compumedics and Medical Developments gained more than eight percent; Optiscan and Pro Medicus were up more than seven percent; Admedus was up 6.4 percent; Acrux, Bionomics, Impedimed, LBT, Pharmaxis and Viralytics climbed more than five percent; Dimerix and Polynovo were up four percent or more; Nanosonics, Neuren, Oncosil, Opthea and Orthocell climbed three percent or more; Benitec, Cochlear, ITL and Mesoblast rose more than two percent; CSL, Resmed and Starpharma were up more than one percent; with Sirtex up 0.1 percent.

Genetic Signatures led the falls, down four cents or 12.1 percent to 29 cents with 10,000 shares traded.

Universal Biosensors lost 7.9 percent; Cyclopharm fell 3.2 percent; Clinuvel, Ellex and Factor Therapeutics shed more than two percent; with Avita down 1.7 percent.

ELASTAGEN, BRANDON CAPITAL, MRCF GBS VENTURES

Sydney skin and wound repair company Elastagen says it will be acquired by Allergan for \$US95 million (\$A120.3 million), plus contingent and commercial payments.

Elastagen said that its product was based on recombinant tropoelastin, the precursor of elastin which was "a key component of youthful skin" and would be a treatment for acne scars, stretch marks, aesthetic skin repair and wound repair.

The company said the Dublin, Ireland-based Allergan PLC was the manufacturer of Botox. Elastagen said it was part of the Medical Research Commercialisation Fund portfolio, managed by Brandon Capital Partners and had received investment from a syndicate of venture groups including Amorepacific Ventures, Brandon Capital, Cell Innovation Partners, Cicada Innovations, GBS Ventures, Korea Investment Partners and the Wellcome Trust, as well as receiving significant support from Federal Government grants and the New South Wales Government Medical Devices Fund.

The company said it was one of the inaugural recipients of a Medical Devices Fund grant in 2013 and would be the first to repay the funding amount.

Elastagen said that its tropoelastin was "identical to that present in human tissue". Allergan chief commercial officer Bill Meury said that his company's Juvederm collection of fillers had sales of more than \$1 billion globally and was one of the fastest growing parts of the company's aesthetics business.

"This acquisition and the development of a next generation of injectables based on this technology will ensure Allergan offers innovative filler products for years to come," Mr Meury said.

Elastagen founding scientist Prof Anthony Weiss said the technology had "come a long way from the lab bench at the University of Sydney towards developing products for patients around the world".

Elastagen said the transaction was subject to customary conditions.

Elastagen is a private company.

IMUGENE

Imugene says its 18-patient phase Ib HER-Vaxx cancer vaccine IMU-131 trial is "showing early promise in patients with metastatic gastric cancer".

Imugene said that feedback from clinicians running the study has been positive with no safety, toxicity or tolerability issues in the first cohort dosing of patients.

Imugene lead investigator Prof Christoph Zielinski said the cohort review committee reviewed the results and recommended dose escalation.

Last year, Imugene said the open-label, dose-escalation study was designed to assess the safety, tolerability and immunogenicity of IMU-131, to show how well the vaccine was directing production of HER2 antibodies in patients (BD: Nov 7, 2016; Aug 31, 2017). The company said at that time that the combination HER-Vaxx and chemotherapy trial would interrogate three dose levels and evaluate the booster schedule to help determine the optimal recommended dosing for a 68-patient phase II study.

Today, Prof Zielinski said that "unlike Herceptin and Perjeta, which are injected synthetic antibody products, HER-Vaxx activates the patient's own immune system to produce a continuous supply of cancer-targeting antibodies and induce a response against the tumors as we see with Herceptin and Perjeta".

Imugene said the clinical results indicated that IMU-131 induced "strong immune responses in patients, with antibodies to the target cancer biomarker HER2/neu strongly evident in validated assays".

Imagene was up 0.4 cents or 28.6 percent to 1.8 cents with 129.1 million shares traded.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says that immune response controls could lead to new drugs for inflammatory diseases such as Crohn's disease and multiple sclerosis. WEHI said that faults in the critical NOD2 immune pathway enabled inflammation to continue unchecked.

The Institute said that the NOD2 pathway detected and responded to bacterial invaders by releasing inflammatory signals to fight the infection and inflammatory diseases such as multiple sclerosis, the inflammatory bowel disease Crohn's disease and inflammatory skin diseases were linked to faults in how the NOD2 pathway was regulated.

WEHI said the research, entitled 'IAPs regulate distinct innate immune pathways to coordinate the response to bacterial peptidoglycans' was published in Cell Reports and was available at: http://www.cell.com/cell-reports/fulltext/S2211-1247(18)30041-X.

The research article said that NOD2 was "an intracellular receptor for bacterial peptidoglycan" and the x-linked inhibitors of apoptosis protein (XIAP) ... was the only IAP required for signaling immediately downstream of NOD2."

"... [cellular] IAPs regulate NOD2-dependent autocrine [tumor necrosis factor] signalling in-vivo and highlight the importance of physiological context in the interplay of innate immune signalling pathways," the research article, authored by Prof John Silke, Dr Ueli Nachbur and Che Stafford, said.

Dr Nachbur said that faults in how the NOD2 pathway was controlled could enable the cell to continue to cause inflammation long after the bacterial threat passed, leading to chronic inflammatory diseases.

"Inflammation occurs when our immune cells release inflammatory messengers, or cytokines, which is a normal response to disease," Dr Nachbur said.

"However when too many cytokines are produced, inflammation can get out-of-control and damage our own body, a hallmark of inflammatory diseases," Dr Nachbur said.

Mr Stafford said the research team showed that XIAP initiated inflammation via the NOD2 pathway.

"Once the NOD2 pathway trigger is initiated, the cells need a second, amplifying step to complete a full-strength immune response," Mr Stafford said.

"Knowing the key players in the entire NOD2 pathway, from initiators to enhancers, would pave the way for new strategies to treat inflammatory diseases," Mr Stafford said.

"Targeting key components of the NOD2 pathway shows promise as a way of switching off ongoing inflammation associated with diseases such as Crohn's disease and multiple sclerosis," Mr Stafford said.

"In 2015 our research team showed that blocking a different protein in the NOD2 pathway could halt inflammation, and was able to halt the progression of multiple sclerosis in a preclinical model," Mr Stafford said. "So it is very exciting to identify other potential targets for treating these diseases," Mr Stafford said.

Dr Nachbur said that clarifying how the NOD2 pathway was regulated on a molecular level was important for developing new treatments for inflammatory diseases.

"Chronic inflammatory conditions such as Crohn's disease and multiple sclerosis have a very significant impact to people's lives and new, targeted treatments are urgently needed," Dr Nachbur said.

"XIAP has other roles in the cell, such as regulation of cell death, so it is a tricky target for treating inflammatory diseases," Dr Nachbur said.

"However these new discoveries provide us with vital information to develop new treatment strategies that could lead to a safe and effective way of switching off inflammation for treating disease," Dr Nachbur said.

AVIRAGEN THERAPEUTICS (FORMERLY BIOTA PHARMACEUTICALS)

Aviragen says it postponed its Vaxart merger extraordinary general meeting from February 6 to February 9, 2018 to give voters more time to vote for the proposal.

The Concerned Aviragen Shareholders (CAS) Group has told Biotech Daily that it hopes to defeat to merger proposal and spill the board at the annual general meeting scheduled for April 2018.

The CAS Group has criticized the Aviragen board and management for its "track record of value destruction" citing the loss of the \$US231 million BARDA contract and the 90 percent fall in its share value (BD: Oct 31, 2017; Jan 24, 30, 2018).

Today, Aviragen said the February meeting was convened and adjourned "to provide the company's stockholders additional time to consider and vote for [its] proposed merger with Vaxart [and it intended] to reconvene the special meeting on February 9, 2018 at 12pm USEST".

On the Nasdaq, Aviragen fell 0.7 US cents or 1.12 percent to 62 US cents (78.4 Australian cents, equivalent to 9.8 cents before leaving the ASX for the Nasdaq when Biota was trading around \$A1.00) with 293,459 shares traded.

MMJ PHYTOTECH

MMJ says that Canada subsidiary Harvest One Cannabis expects to grow 70 tonnes of dried cannabis flower by the end of 2019.

MMJ said that Harvest One thorough its wholly-owned subsidiary United Greeneries was targeting 20 tonnes of dried cannabis flower capacity by the end of 2018 and 70 tonnes by the end of 2019.

The company said that the Lucky Lake facility, near Saskatoon, Saskatchewan was a 62,000 square feet (5,760 square metres) concrete agricultural facility on 18 acres (7.3 hectares) and was in the final stages of Health Canada approval.

MMJ was up six cents or 14.6 percent to 47 cents with 2.9 million shares traded.

THE HYDROPONICS COMPANY

Hydroponics says it will copy Canada's National Access Cannabis medical marijuana clinic system and hopes to open its first clinic by July 2018.

Hydroponics said that National Access Cannabis was "a leading provider of clinic services to medicinal cannabis patients in Canada" and its model was identified as "a strong fit with the developing Australian market".

The company said that National Access Cannabis offered patient education on licenced producers, strains, methods of consumption and dosing guidelines; partnered with health care professionals, providing education and expert advice as they began prescribing medicinal cannabis; and data collection to facilitate policy and clinical practice decision-making.

Hydroponics said that National Access Cannabis would make its systems implementation manager available onsite in Sydney on secondment to assist with the development and implementation of a clinic roll-out plan.

Hydroponics chief executive officer David Radford said that the medicinal cannabis clinics in Canada were "instrumental in developing the demand side of the business".

"The Australian market has many similarities to the Canadian market at a clinical level, with an identified need for excellence in training and patient support as key success factors to aid market development," Mr Radford said.

Hydroponics was up 4.5 cents or 6.3 percent to 76 cents with 1.35 million shares traded.

RHYTHM BIOSCIENCES

Rhythm says it has immunized mice with the target antigen and preparation of mixed cultures of antibody-producing cells for its Colostat test for colorectal cancer.

Rhythm said the reagent development required further confirmation which was expected by May 2018.

The company said the reagent development program was being conducted with the Commonwealth Scientific and Industrial Research Organisation.

Rhythm was unchanged at 19 cents.

CANN GROUP

The Sydney-based Tribeca Investment Partners says it has become a substantial shareholder in Cann with 7,041,570 shares (5.05%).

The substantial shareholder notice said that Tribeca bought and sold shares between October 10, 2017 and February 5, 2018.

The Tribeca announcement said the largest purchase was on December 12, 2017 when Cann was raising \$78 million at \$2.50 a share (BD: Dec 13, 2017).

Cann was up 31 cents or 12.45 percent to \$2.80 with 764,331 shares traded.

BIOTECH CAPITAL

Naos Asset Management says it has increased its substantial shareholding in Biotech Capital from 15,583,005 shares (12.26%) to 20,698,986 shares (15.89%).

The Martin Place, Sydney-based, Naos said it was the investment manager for "various trustee companies" and the registered holder was Australian Executor Trustees, but yet again failed to cite the cost of the 5,115,981 shares acquired on-market, as required under the Corporations Act 2001 (BD: Feb 24, Jun 14, Aug 1, Nov 14, 2017). Biotech Capital was untraded at 20 cents.