Biotech Daily

Tuesday January 30, 2018

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: GENETIC SIGNATURES UP 14%; OSPREY DOWN 16%**

*** CAS GROUP: 'AUSSIE BIOTA INVESTORS SHOULD OPPOSE AVIRAGEN'**

*** VARIAN OFFERS $1.6b FOR SIRTEX**

*** ANALYTICA TO SENATE: 'PERICOACH BEATS TRANSVAGINAL IMPLANTS'**

*** IMMURON: 'US ARMY SHOWS TRAVELAN REACTIVE TO BACTERIA'**

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*** GENETIC TECHNOLOGIES LOSES DIRECTORS; EGM TRADING HALT**

*** MMJ TAKES $2.5m STAKE IN TORONTO'S DOSECANN**

*** ADMEDUS RECEIPTS UP 29% TO $11.6m; INDIA LAUNCH**

*** IMPEDIMED H1 RECEIPTS DOWN 21% TO $2.4m**

*** MING HAO ZHENG, YING FAN INCREASE, DILUTED TO 6% OF ORTHOCELL**

*** MICHAEL ABOLAKIAN, HISHENK TAKE 9.5% OF KAZIA**

*** WEHI'S PROF JACQUES MILLER WINS $275k JAPAN PRIZE FOR T-CELLS**

MARKET REPORT

The Australian stock market fell 0.87 percent on Tuesday January 30, 2018, with the ASX200 down 52.6 points to 6,022.8 points. Fourteen of the Biotech Daily Top 40 stocks were up, 14 fell, eight traded unchanged and four were untraded. All three Big Caps fell.

Genetic Signatures was the best, up four cents or 13.8 percent to 33 cents with 617,233 shares traded. Bionomics climbed 8.6 percent; LBT rose five percent; Immutep (Prima) and Starpharma improved more than four percent; Acrux, Admedus and Oncosil were up more than three percent; Orthocell rose 2.9 percent; Airxpanders, Neuren, Telix and Universal Biosensors were up more than one percent; with Pro Medicus up 0.4 percent.

Osprey led the falls, down 5.5 cents or 15.9 percent to 29 cents with 3.6 million shares traded. Impedimed fell 12.5 percent; Benitec lost eight percent; Nanosonics, Polynovo, Resmed, Reva and Uscom shed more than two percent; Avita, Clinuvel, Compumedics, CSL, Cyclopharm, Medical Developments and Volpara were down more than one percent; with Cochlear and Mesoblast down by less than one percent.

AVIRAGEN (FORMERLY BIOTA PHARMACEUTICALS)

The Concerned Aviragen Shareholders Group has called on Australian investors in Biota, now Aviragen, to vote against the proposed Vaxart merger and spill the board.

Last week, the Concerned Aviragen Shareholders (CAS) group said that Aviragen had a "track record of value destruction" (BD: Oct 31, 2017; Jan 24, 2018).

In notices to Aviragen and the US Securities and Exchange Commission, the group said it comprised Digirad Corp, East Hill Management Corp, Thomas Clay and others, collectively holding about 8.3 percent of Aviragen.

Today, Investorcom executive John Grau, acting for the group, told Biotech Daily that of Aviragen's 38.65 million shares on issue, about six million shares were held in Australia.

At the time of the 2012 Biota merger with Nabi there were about 10,000 individual shareholders in the company, many of whom did not establish US trading accounts.

With the company devalued by 90 percent Biotech Daily believes many holdings are unmarketable parcels below $500 in value, but the shares count as votes.

The group urged Australian shareholders to go to its website, read the materials, download the proxy voting form and vote against the merger with Vaxart.

The website is at: http://concernedaviragenshareholders.net.

Aviragen has urged shareholders to vote for the merger (BD: Oct 31, 2017).

East Hill principal Thomas Clay said that the merger vote would be held on February 6, 2018 and proxy forms needed to be received before that date.

Mr Clay said that Aviragen had scheduled its annual general meeting for April 11, 2018 and the Concerned Aviragen Shareholders group expected to propose new directors to replace the current board as well as management.

Last week, the CAS group said "we have been extremely dissatisfied with the performance of the company under its current board and we believe that the proposed merger is not in the best interest of the company or its stockholders".

"We believe Aviragen management has a track record of value destruction and that the board has failed to take appropriate actions and should be held accountable," the group said.

In 2012, Biota moved from the ASX to the Nasdaq to merge with Nabi Pharmaceuticals for its $US54 million in cash, settling for $US27 million, and was renamed Biota Pharmaceuticals and then Aviragen (BD: Apr 23, Sep 18, Oct 26, 30, Nov 2012).

Following its move to the US, Biota lost its $US231 million contract with the US Office of Biomedical Advanced Research and Development Authority to further develop its laninamivir anti-influenza drug with BARDA citing "concerns about the project with regard to the product manufacturing, clinical study enrolment pace, costs, and contractor performance" (BD: Apr 1, 2011; Apr 30, May 1, May 9, 2014).

Today, the CAS group said that independent proxy voting advisory firm Institutional Shareholder Services Inc (ISS) recommended that stockholders vote against the Vaxart merger saying that Aviragen shares "currently trade at a small fraction of the company's implied post-merger valuation, which seems to indicate that management has not made a sufficiently compelling argument that justifies the terms of the deal".

The group quoted ISS saying "Aviragen would be ceding control to a company with significant net debt, a pipeline of potentially rewarding but still very early stage trials, and that is likely in need of future possibly dilutive funding … [and] "an alternative would be for shareholders to reject the deal in the hope that the board finds another transaction that adequately compensates shareholders for Aviragen's assets."

Last night on the Nasdaq, Aviragen slipped 0.87 US cents or 1.43 percent to 60 US cents (74.1 Australian cents, equivalent to 9.3 cents pre-merger when the company was trading at $A1.00) with 356,133 shares traded.

SIRTEX MEDICAL

Sirtex says it had entered into a binding scheme of implementation with the Palo Alto California Varian Medical Systems to acquire it for $1,561,645,260 or $28.00 a share.
Sirtex made the announcement to the ASX after the market closed.
Full details will be published tomorrow.
Sirtex last traded at $18.83.

ANALYTICA

Analytica has told a Senate inquiry that better pelvic floor exercises using its intra-vaginal Pericoach system could obviate the need for had transvaginal mesh implants.
Analytica said it sent a submission to a Australian Senate 'Inquiry into the number of women in Australia who have had transvaginal mesh implants and related matters'.
The company said that pelvic floor exercise might obviate the need for surgical intervention and that "many women may have undergone surgery unnecessarily".
Analytica said that accepted clinical guidance recommended pelvic floor exercises as conservative treatment before considering mesh implant surgery, but the exercises could be difficult to do correctly and were not done regularly.
The company said that its Pericoach monitoring system overcame these issues "by providing the patient with motivation, biofeedback on strength improvements, and can tell the patient if she's performing her exercises correctly".
Analytica said that the American College of Physicians, and the American Urologic Association and Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction had treatment guidelines for implant surgeries, with recommendations that the patient attempt conservative treatments before surgical interventions were considered, including diet, general exercise and pelvic floor muscle exercises.
Analytica said that pelvic floor muscle exercises were invented by Dr Arnold Kegel in the US in the 1940s and were referred to as Kegel exercises and while "proven to reduce the incidence of stress urinary incontinence, and in many cases, eliminate it completely" but they needed to be done regularly and correctly.
The company said the exercise could also benefit pelvic organ prolapse, faecal incontinence lower back pain and improve sexual function.
Analytica said that 37 percent of Australian women had urinary incontinence with "a staggering 70 percent not speaking to their clinicians about their condition" making personalized treatments necessary to mitigate the growing prevalence and economic burden as the population ages.
The company said that half of all women did not contract their pelvic floor muscles correctly with verbal or written instructions and with limited general practitioner time with patients and women waiting years before speaking to a clinician about their urinary incontinence, there was "a serious gap in clinical treatment guidance".
Analytica said that many women received just a brochure describing how to do their exercises, or read about it in women's magazines and blogs and very few received supervised training, a direct contributing factor to the growing health system expenditure for urinary incontinence which is projected to rise to $450 million by 2020.
The company said that women were "confused by a range of claimed Kegel exercise aids that simply don't work".
Analytica said that universal use of its Pericoach system in pre-pregnancy and post-partum women "would save … the community billions of dollars in environmentally unfriendly incontinence pads, risky surgical treatments, and nursing home costs".
Analytica was untraded at 0.6 cents.

IMMURON

Immuron says a US Department of Defense study shows that its Travelan is reactive to 180 clinical isolates of Campylobacter, enterotoxigenic Escherichia coli and Shigella.

Immuron said that the study by the US Armed Forces Research Institute of Medical Sciences in Bangkok, Thailand investigated the immuno-reactivity of the over-the-counter Travelan to infectious bacterium strains from Southeast Asia.

The company said that the 60 bacterial isolates from each of the three pathogenic bacteria were collected from infected patients located in Bhutan, Cambodia, Nepal and Thailand between 1993 and 2016, and held in the Institute's library of infectious diseases were tested by a Western blot analysis.

Immuron said that Travelan showed "particularly strong reactivity to 60 clinical isolates of personnel infected with enterotoxigenic Escherichia coli and 60 personnel infected with Shigella".

"When compared to the control, researchers found that the antibodies within Immuron's Travelan product were reactive to all 180 clinical isolates from these infected individuals," Immuron said.

"The ability of Travelan to bind and potentially neutralize these bacteria, highlights the broad-spectrum recognition of surface antigens on potentially debilitating and even life-threatening bacteria," the company said.

Immuron chief executive officer Dr Jerry Kanellos said that Travelan had "proven its reactivity to a multitude of clinically relevant bacterium strains within Southeast Asia including ETEC, Campylobacter and Shigella".

Dr Kanellos said that the research was the first of three research projects in collaboration on with the US Department of Defense with more due in the next few months.

"Travelan's reactivity to various forms of these infectious diseases makes it a valuable asset to foreign government officials looking to protect employees stationed in these regions, as well as consumers who want to preserve their health while travelling abroad," Dr Kanellos said.

"In addition to consumer purchases, government and organizational adoption of Travelan represents a significant revenue opportunity for Immuron, and one that we seek to capitalize upon as we market the product more broadly," Dr Kanellos said.

Immuron said that a prophylactic treatment protecting against enteric diseases, specifically Shigella, was a high priority objective for the US Army, supported under the Military Infectious Diseases Research Program and for use in endemic areas of the world.

The company said that Shigella was estimated to cause up to 165 million cases of disease worldwide, resulting in 600,000 deaths a year and was prevalent in both sub-Saharan Africa and South Asia.

Immuron was up 6.5 cents or 28.3 percent to 29.5 cents with 1.2 million shares traded.

AVITA MEDICAL

Avita says five abstracts on its Recell burns treatment have been accepted for presentation at the American Burn Association Meeting in Chicago in April 2018.

Avita said that the meeting would be the first venue in which investigators would present the detailed efficacy and safety data from two trials used to support its US pre-market approval application for the treatment of burn injuries as well as other clinical studies and modelling showing the health economic benefits of Recell.

Avita chief executive officer Dr Michael Perry said the abstracts "highlight the depth of the positive clinical data supporting the medical and economic benefits of Recell".

Avita fell 0.1 cents or 1.8 percent to 5.4 cents with 9.85 million shares traded.

PHARMAUST

Pharmaust says it has identified a reformulation method to prepare monepantel for cancer trials improving its taste and dosing, taste masking and oral bioavailability.

In 2017, Pharmaust contracted the Vancouver, British Columbia-based BRI Biopharmaceutical Research to reformulate monepantel for its clinical trials, to build on efforts from the Nottingham, England-based Juniper Pharma Services which reformulated the liquid monepantel which was unpalatable to humans and dogs in the form of Zolvix into capsules (BD: Jul 11, 2016; Jun 27, 2017).

Today, the company said that micronization ground monepantel into a powder that could be processed and packaged into capsules or tablets and depending on the size could deliver more than 10 times more drug than the current formulation.

Pharmaust said that animals and human taste studies showed that dry powder monepantel was “much more palatable than the liquid form” and micronized monepantel was amenable to conventional taste-masking that could further improve palatability.

The company said that BRI was optimizing the micronization method to identify the final formulation and once established, the formulation would be scaled to produce sufficient drug for clinical trial expected by July 2018.

Pharmaust was up 0.1 cents or 1.5 percent to 6.9 cents.

PAINCHEK (FORMERLY EPAT TECHNOLOGIES)

Painchek says the android version of its mobile pain assessment application has been completed and is undergoing testing prior to general release.

Painchek said the android version had the same technology and functionality as the Apple Iphone version and was expected to be available to consumers by July 2018.

Painchek chief executive officer Philip Daffas said that availability on both Apple and android platforms provided access to more than 80 percent of the Australian aged care market and more than 99 percent of the global mobile telephone consumer market.

Painchek was unchanged at 6.2 cents with 2.4 million shares traded.

MMJ PHYTOTECH

MMJ says it will acquire a “strategic” $C2.5 million ($A2.51 million) stake in the privately-owned, Toronto-based Dosecann Inc.

MMJ said the $C2.5 million placement in secured convertible debenture units would “further solidify [its] position in the Canadian cannabis sector, leveraging a number of existing operational synergies within [its] current investment portfolio”.

The company said that Dosecann was a consumer healthcare company developing of cannabis-based health products and was planning construction of a 45,000 square feet (4180.6 square metres) pharmaceutical level production facility and intending to secure licenced dealer status by May 2018, as well as applying to become a licenced producer.

MMJ said that the debentures were convertible into shares and warrants in Dosecann based on a pre-money valuation of Dosecann at $C11.5 million, with each debenture unit consisting of one eight percent unsecured debenture, maturing in two years with interest payable semi-annually on June 30 and December 31 of each year, as well as 500 share purchase warrants.

The company said the debentures would be convertible at $C1.00 per Dosecann share.

MMJ said that each warrant entitled the holder to acquire one share at an exercise price of $1.20 at any time up to 24 months following the closing date of the offering.

MMJ was up 1.5 cents or three percent to 52 cents with 1.25 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says chairman Dr Malcolm Brandon and director Grahame Leonard have resigned and a trading halt has been requested for the board spill meeting.

In December, the company said it had received a notice under Section 249D of the Corporations Act 2001 calling for an extraordinary general meeting to remove Dr Brandon, Mr Leonard and chief executive officer Eutillio Buccilli as directors and appoint Samuel Xue Lee, Peter Irwin Rubenstein and Jerzy Muchnicki in their place (BD: Dec 1, 2017).

The company said that the notice was received from Antanas Guoga, Ugnius Simelionis, Security and Equity Resources, SH Rayburn Nominees Pty Ltd, Irwin Biotech Nominees Pty Ltd, MJGD Nominees Pty Ltd and Samuel Lee who claimed to hold about 5.5 percent of the issued shares of the Company.

Today, Genetic Technologies said the trading halt was “pending an announcement on the outcome of the results of the … meeting” tomorrow, January 31, 2017 at 10am.

The company thanked Dr Brandon and Mr Leonard for their contributions during their respective periods of appointment.

Genetic Technologies fell 0.05 cents or 3.1 percent to 1.55 cents with 8.8 million shares traded.

ADMEDUS

Admedus says that receipts from customers for the year to December 31, 2017 was up 29.0 percent to $11,647,000 compared to previous corresponding period.

Admedus said that receipts for the three months to December 31, 2017 improved 55.5 percent to $6,484,000, including revenue of $2.1 million for its Cardiocel Adapt bovine cardiac tissue products and $4.2 million from sales of its infusion sets.

The company said it had a cash burn for the three months of $3,388,000, cash and cash equivalents of $8,255,000 at December 31, 2017, as well as a $10 million debt facility.

Admedus said that Cardiocel had been launched in India today (BD: Nov 22, 2017).

Admedus was up one cent or 3.85 percent to 27 cents.

IMPEDIMED

Impedimed says receipts from customers for the six months to December 31, 2017 fell 21.4 percent to $2,359,000 compared to the previous corresponding period.

In its Appendix 4C quarterly report Impedimed said that it received $1,250,000 in receipts from customers for the six months compared to $1,544,000 in the six months to December 31, 2016.

Impedimed chief executive officer Richard Carreon said that in the three month period the company’s Sozo diagnostic had been cleared by the US Food and Drug Administration for fluid management of congestive heart failure patients, which was “a significant achievement and milestone for the company”.

“During the quarter we successfully commenced the first commercial sales of Sozo with L-Dex [for lymphoedema] in the US market,” Mr Carreon said.

“I’m delighted with the early response to Sozo and pleased with our ability to convert existing L-Dex customers and expand our footprint in a number of cancer centres in the short amount of time since we launched Sozo,” Mr Carreon said.

Impedimed said it had a cash burn for the three months to December 31, 2017 of $5,571,000 with $42,406,000 in cash at December 31, 2017

Impedimed fell 12 cents or 12.5 percent to 84 cents.

ORTHOCELL

Prof Ming Hao Zheng and Ying Fan said they have increased their holding from 7,063,608 shares to 7,392,715 shares and been diluted to 6.72 percent.
Orthocell chief scientific officer Prof Zheng said that 20,284 shares were acquired in a placement at 34.5 cents in February 2016 and 308,823 shares were acquired in a placement at 34 cents in December 2017.
The notice said that the shares were held with Jessica Zheng and Monica Zheng.
Orthocell was up one cent or 2.9 percent to 35 cents.

KAZIA THERAPEUTICS (FORMERLY NOVOGEN)

Michael Abolakian says that through Hishenk Pty Ltd he has increased his substantial holding in Kazia from 3,821,173 shares (7.8%) to 4,582,111 shares (9.5%).
The Artarmon, Sydney-based Mr Abolakian said the shares were held by Hishenk Pty Ltd and Hishenk Super Fund, which acquired 760,938 shares for $354,660 or 46.6 cents a share, between January 15 and 29, 2018.
Kazia was up 6.5 cents or 11.1 percent to 65 cents.

JAPAN PRIZE FOUNDATION, THE WALTER AND ELIZA HALL INSTITUTE

The Japan Prize Foundation says Walter and Eliza Hall Institute's Prof Jacques Miller and Emory's Prof Max Cooper have won the Japan Prize for Medical and Medicinal Science.
A spokesperson for the Foundation told Biotech Daily that Prof Miller and Dr Cooper would share the YEN50 million ($A550,000) prize for their discovery of T and B lymphocytes which protecting bodies from infection.
The Foundation said that Prof Miller discovered that T-lymphocytes attacked virus-infected cells, which "paved the way for decades of developments in lifesaving immunotherapies".
The Walter and Eliza Hall Institute website said that in 1966, Prof Miller returned to Australia, having been invited by then director Prof Gustav Nossal, to be head of the experimental pathology unit and working with Dr Graham Mitchell, set out to prove that the thymus produces immune cells, to be known as T-cells that were essential for the immune response.
"What we discovered was that there are in fact two types of white blood cells: T-cells, which are produced in the thymus, and B cells which are produced in the bone marrow," Prof Miller said.
"Furthermore, we discovered that B-cells are the cells that produce antibodies, and that T-cells actually interact with the B-cells to help them produce antibodies," Prof Miller said.
The Foundation media release said that Prof Cooper and Prof Miller's discovery established the basic concepts underlying modern immunology.
The Foundation said the award ceremony would be held in Tokyo on April 18, 2018 with a YEN50 million Japan Prize for resources, energy, environment and social infrastructure prize awarded to Dr Akira Yoshino for his development of lithium ion batteries.
The media release said that the prize evaluated 13,000 nominators comprised of prominent scientists and researchers from across the globe.
The Foundation said that each November it announced two specific fields to be awarded in two years' time and opens nominations with the 2019 Japan Prize to be awarded to 'materials, production' and 'biological production, biological environment'.