Biotech Daily

Monday February 12, 2018

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: USCOM UP 15%; FACTOR DOWN 5%**

*** FDA EXPANDS AVITA RECELL COMPASSIONATE USE TO 88 PATIENTS**

*** IMUGENE ANTI-PD1 MIMOTOPE VACCINE PRE-CLINICAL READY**

*** INVION $2.5m RIGHTS ISSUE AT 93% DISCOUNT**

*** JAPAN PATENT FOR REGENEUS HUMAN, ANIMAL CANCER VACCINE**

*** CAS CAPITULATES FOR AVIRAGEN 9% MORE IN VAXART MERGER**

*** ACTINOGEN XANADU ALZHEIMER'S TRIAL 41% ENROLED**

*** BRITISH, IRISH HYPERTENSION SOCIETY BACKS USCOM BP+**

*** MEDICAL DEVELOPMENTS PLACES SPACERS AT WALGREENS**

*** GENETIC TECHNOLOGIES, ASX DISCUSS BLOCKCHAIN IMPACT**

*** NUHEARA APPOINTS EX-MICROSOFT KATHRYN FOSTER DIRECTOR**

MARKET REPORT

The Australian stock market fell 0.3 percent on Monday February 12, 2018 with the ASX200 down 17.3 points to 5,820.7 points. Nine of the Biotech Daily Top 40 stocks were up, 19 fell, 11 traded unchanged and one was untraded.

Uscom was the best, up 3.5 cents or 14.9 percent to 27 cents with 895,584 shares traded. Actinogen climbed 10 percent; Avita was up 3.6 percent; Compumedics and Medical Developments rose two percent or more; Cochlear, Impedimed and Orthocell were up more than one percent; with Resmed, Sirtex and Volpara up by less than one percent.

Factor Therapeutics led the falls, down 0.2 cents or 5.3 percent to 3.6 cents with 795,850 shares traded, followed by Osprey down five percent to 28.5 cents with 463,246 shares traded. Benitec fell 4.35 percent; Mesoblast, Oncosil, Psivida, Starpharma and Universal Biosensors lost more than three percent; LBT and Viralytics shed more than two percent; Airxpanders, Bionomics, Genetic Signatures, Pharmaxis, Pro Medicus and Telix were down one percent or more; with Clinuvel, CSL, Neuren and Polynovo down by less than one percent.

AVITA MEDICAL

Avita says the US Food and Drug Administration has approved a 20-patient increase for the use of Recell under the compassionate use investigational device exemption.
Avita said that the FDA had approved the use of its “autologous cell harvesting device” to up to 88 patients with life-threatening injuries, including severe burns.
The company said it was the fifth expansion to the compassionate use protocol for Recell for patients who had insufficient healthy skin for standard skin grafting treatment of injuries and whose treating physicians believed there to be no suitable alternative treatment.
The company said that 64 compassionate use cases had used Recell, with two abstracts relating to cases accepted for presentation at the American Burn Association meeting to be held in Chicago, Illinois from April 10 to 13, 2018.
Avita said the presentations would describe the use of Recell for patients with partial thickness facial burns and with extensive burn injuries.
Avita chief executive officer Dr Michael Perry said the company appreciated the FDA the expansion of the compassionate use program “which highlights the critical unmet need among patients with life-threatening injuries such as severe burns”.
In 2017, Avita submitted a pre-market approval application for Recell for the treatment of burn injuries to the FDA, and it expected the review to be completed by October 2018.
Avita was up 0.2 cents or 3.6 percent to 5.7 cents with 1.4 million shares traded.

IMUGENE

Imugene says it has completed early development of a new mimotope vaccine targeting “the billion-dollar blockbuster anti-PD-1 immuno-oncology market”.
Imugene said that it had filed a new method of treatment patent with the Australian Patent Office to provide protection across a range of immunotherapies, including cancer vaccines such as its HER-Vaxx.
The company said it would begin pre-clinical development to test the vaccine for efficacy and safety, following 18 months of research with the Medical University of Vienna.
The company said that a mimotope induced an antibody reaction against a target, in this case the regulatory immune check-point PD-1, or programmed cell death protein-1.
Imugene said that mimotope-induced antibodies might have advantages over synthetic antibodies including safety, longer responses, memory and cost, with the check-point inhibitor market dominated by two monoclonal antibody drugs, Opdivo and Keytruda, which had sales in 2017 of $US4.95 billion and $US3.81 billion, respectively, and targeted PD-1, “a key switch of the immune system’s ability to find and eliminate cancerous cells”.
The company said that research led by its chief scientific officer Prof Ursula Wiedermann identified mimotope peptides that when incorporated into its immune-therapeutic vaccine delivery platform, generated antibodies that bound to the PD-1 biomarker.
Imugene said that PD-1 antibodies blocked a protective mechanism on cancer cells, allowing the immune system to destroy those cancer cells.
The company said that the concept of teaching and inducing the body to generate its own antibodies against PD-1 expressing cells was “a paradigm shift in immuno-oncology” it was the first report of treating cancer by this method, and positioned it “to be a new and competitive player in the immuno-oncology revolution in cancer therapy”.
Imugene chief executive officer Leslie Chong said that “on announcing our mimotope program in January 2016 we were cautious given the early stage of the research”.
“However, the progress made by the entire team raises the anticipation that a paradigm shift in cancer treatment is in play,” Ms Chong said.
Imugene climbed 0.6 cents or 35.3 percent to 2.3 cents with 269.3 million shares traded.

INVION

Invion says it expects to raise $2.5 million through a fully-underwritten, eight-for-27 non-renounceable rights issue at a 93 percent discount to its last share price.

Invion chief executive officer Dr Greg Collier told Biotech Daily that the 0.2 cents pricing was approved at the November annual general meeting when it was trading at that price (BD: Nov 30, 2017).

“The share price has improved for 0.2 cents at the time of the meeting to a high of three cents with no company announcements other than the Cho Group’s involvement with the company,” Dr Collier said.

In a media release, Invion said that the rights issue was part of the strategic transaction with the Cho Group announced in last year (BD: Aug 31, 2017).

The company said that the offer price of 0.2 cents was a discount of 90.93 percent to the theoretical ex-rights price of 2.21 cents, a 92.85 percent discount to the last traded price on February 9 of 2.8 cents and a 91.11 percent discount to the five day volume weighted average price at February 9, 2018.

Last year, Invion said it would licence “new generation photo dynamic therapy” for cancers from the Hong Kong’s Cho Group for $5.5 million in shares at 0.2 cents a share, when Invion had a market capitalization of $2,911,931 (BD: Aug 31, 2017).

Invion said at that time, that the Cho Group would underwrite a non-renounceable pro rata rights offer to raise $2.5 million for working capital and the costs of the transaction.

Today, the company said that the record date for the rights issue would be February 15, the offer would open on February 19 and close on March 8, 2018.

Invion fell 0.4 cents or 14.3 percent to 2.4 cents with 29.1 million shares traded.

REGENEUS

Regeneus says the Japanese Patent Office has grant a patent covering the use of cancer vaccine technology for a range of cancers in humans and animals.

Regeneus said the patent, ‘Vaccines for the treatment or prevention of cancer and compositions for enhancing vaccine efficacy’ would provide protection in Japan until 2033.

The company said that corresponding patents had been granted in Australia and were being pursued for grant in other territories including the US and Europe.

Regeneus said the technology used a patient’s own cancer cells combined with an immune-stimulant designed to re-educate the immune system to target cancer cells in existing and new tumors.

The company said that the patent supported its human RGSH4K and animal Kvax clinical programs with RGSH4K in a 21-patient phase I safety study on a range of tumors at Sydney’s Northern Cancer Institute (BD: Oct 27, 2015).

The company said that a US canine osteosarcoma study showed that Kvax administered after limb amputation was safe and well tolerated and appeared to confer increased progression-free interval and improved survival compared to historically treated dogs with osteosarcoma treated with limb amputation only.

Regeneus said Kvax was the subject of a canine lymphosarcoma study in combination with chemotherapy at Sydney’s Small Animal Specialist Hospital.

The company said that the technology was developed by researchers at Sydney’s Royal North Shore Hospital Bill Walsh Translational Cancer Research Laboratory.

Regeneus said that in a rat brain tumor model, vaccination led to remission rates of up to 60 percent, significantly extended survival in all vaccinated animals and re-challenging animals in remission showed 100 percent tumor rejection, indicating acquired immunity.

Regeneus was up one cent or 8.7 percent to 12.5 cents.

AVIRAGEN THERAPEUTICS (FORMERLY BIOTA PHARMACEUTICALS)

The Concerned Aviragen Shareholders (CAS) Group says it has withdrawn its concerns over the Aviragen-Vaxart merger following an improved offer.

In January, the CAS Group said that the board and management of Aviragen had destroyed value in the company citing the loss of the $US231 million Biomedical Advanced Research and Development Authority (BARDA) contract, other clinical trial failures and the fall in share price (BD: Jan 24, 30, 2018).

The CAS Group, composed of Digirad Corp, East Hill Management Co and Thomas Clay, with other investors said at that time that it was "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, calling on Australian investors to vote against the merger and spill the board.

Over the weekend, Aviragen published a statement by the CAS Group that it had accepted an improved offer from Vaxart giving Aviragen shareholders 49 percent of the merged company instead of 40 percent.

The meeting was further adjourned to February 13, 2018.

The CAS Group said it had "carefully reviewed and considered the improved terms of the proposed merger … [and] in light of these recent developments, the CAS Group is now in support of the merger".

The CAS Group said it had settlement agreement with Aviragen and Vaxart in connection with the special meeting and it would vote for the merger, the share consolidation and withdrew its nomination of directors in connection with the next annual meeting and agreed to vote in favor of the directors nominated for election by the Aviragen board, along with payment by Aviragen to the CAS Group for "reasonable out-of-pocket expenses in connection with, among other things its solicitation in connection with the special meeting, not to exceed $US200,000".

In January, 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" (BD Jan 30, 2018).

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."

On Friday on the Nasdaq, Aviragen fell three US cents or 3.82 percent to 76 US cents (97.1 Australian cents, equivalent to 12.1 cents pre-merger when the company was trading at $A1.00) with 2.9 million shares traded.

ACTINOGEN MEDICAL

Actinogen says it has enrolled 72 of the proposed 174 patients in its Xanadu safety and efficacy trial of Xanamem for Alzheimer's disease.

Actinogen said that more than 30 patients had completed the study, including the 12-week treatment period and the four-week follow-up.

The company said it expected to enrol the last patient by October this year.

Actinogen was up half a cent or 10 percent to 5.5 cents with 7.5 million shares traded.

USCOM

Uscom says its BP+ central blood pressure monitor has been approved for specialist use by the British and Irish Hypertension Society.
Uscom said the approval followed independent evaluation of the technology and associated clinical evidence by Society experts.
The company said that the Society provided “the only independent, peer-reviewed list of blood pressure monitors that is not governed by commercial interest”.
Uscom said the BP+ was approved under the specialist use category, which was “a de facto standard for [blood pressure] monitors and … a key endorsement for large-scale purchasing groups”.
The company said that the BP+ received Conformité Européenne (CE) mark in December and was undergoing review for China US regulatory approvals, expected later this year (BD: Dec 20, 2017).
Uscom chief executive officer Prof Rob Phillips said the BP+ was “a sophisticated clinical technology that is changing the way we measure and manage hypertension, and is rapidly emerging as the global standard of care in this area of specialty”.
Uscom climbed 3.5 cents or 14.9 percent to 27 cents.

MEDICAL DEVELOPMENTS

Medical Developments says it has a “ranging” deal with the Deerfield, Illinois-based Walgreens for its compact anti-static asthma space chamber.
Medical Developments said that Walgreens was the second-largest pharmacy chain in the US with about 9,000 shops.
The company said Walgreens had placed its first orders and was distributing the product.
Medical Developments said its space chamber would be allocated to 2,000 Walgreens shops, supplied by Amerisource Bergen.
Medical Developments chief executive officer John Sharman said the company had been “working towards securing a ranging deal from Walgreens for almost two years”.
“Part of the reason Walgreens entered this deal is because we are gaining rapid acceptance for the quality of our product and our product offering amongst pharmacies in the US,” Mr Sharman said.
“We have a world class respiratory device product range and we have a significant price and reimbursement advantage over competitor products in the US,” Mr Sharman said.
Medical Developments was up 15 cents or two percent to $7.72.

GENETIC TECHNOLOGIES

Genetic Technologies says it is in discussions with the ASX on the effect of an alliance with Blockchain Global on Listing Rule 11.1 on the nature or scale of its operations.
Genetic Technologies said that the discussions related to whether a strategic alliance with Blockchain for its digital technology to provide efficiencies and new opportunities leveraging its existing genomics business would result in a change of activities.
The company said that while the discussions continued, the ASX required that it remain in a suspension.
Last week, acting executive chairman Dr Paul Kasian said that “Embracing new technologies such as blockchain to provide greater efficiencies in how tests are created, stored and passed on to patients, researchers and big Pharma may provide a quantum leap in efficiencies and opportunities” (BD: Feb 5, 2018).
Genetic Technologies last traded at 1.55 cents.

NUHEARA

Nuheara says it has appointed former Microsoft and Amazon executive Kathryn Foster as a director.

Nuheara said that Ms Foster was previously Microsoft's online supply chain director of electronic commerce strategy and head of sales and marketing.

The company said that Ms Foster had more than 20 years' experience with internet-based businesses, starting in the late 1990s on Windows Update.

Nuheara said that Ms Foster set business vision, strategy and drove the technical execution around digital and physical supply chain technology for Xbox Games.

The company said that Ms Foster held a Bachelor of Science from Oregon State University.

Nuheara was unchanged at 5.7 cents with 3.75 million shares traded.