Biotech Daily

Tuesday June 2, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: UNIVERSAL BIOSENSORS UP 14%, PRANA DOWN 24%**

*** VIRALYTICS: 'COMPLETE RESPONSE IN 8 CAVATAK PATIENTS'**

*** CIRCADIAN, ELI LILLY: 'IMC-3C5 SAFE, POTENTIAL CANCER EFFICACY'**

*** NOVOGEN RIGHTS ISSUE RAISES $18m, TAKES TOTAL TO $33m**

*** CLINICAL TRIAL BACKS DORSAVI VIMOVE SYSTEM FOR LOW BACK PAIN**

*** DORSAVI SIGNS UK PHYSIOTHERAPY PLAN**

*** IQ3 TO RAISE $100m FOR RELATED FUND**

*** SIMAVITA SIGNS BUNZL FOR AUSTRALIAN SIM DISTRIBUTION**

*** FLINDERSFERTILITY ADOPTS REPRODUCTIVE HEALTH EMBRYOCELLECT**

*** CELLMID, TAIWAN'S MAYWUFA HAIR GROWTH CONTRACT**

*** CORTENDO TAKES 8.5% OF ANTISENSE**

*** BRAIN RESOURCE NASDAQ LISTING, NAME CHANGE**

*** CORRECTION: AGENIX**

MARKET REPORT

The Australian stock market fell 1.73 percent on Tuesday June 2, 2015 with the S&P ASX 200 down 99.4 points to 5,636.0 points. Ten of the Biotech Daily Top 40 stocks were up, 15 fell, 12 traded unchanged and three were untraded. All three Big Caps fell.

Universal Biosensors was best, up 4.5 cents or 14.1 percent to 36.5 cents with 381,379 shares traded. Antisense climbed 9.1 percent; IDT rose six percent; Clinuvel was up five percent; Cellmid improved 4.35 percent; Starpharma was up 3.85 percent; Impedimed, Mesoblast and Pharmaxis rose more than two percent; with Actinogen up 1.3 percent.

Yesterday's best, Prana, led the falls, down six cents or 24.0 percent to 19 cents with two million shares traded, followed by Prima down 17.35 percent to 8.1 cents with 43.3 millions shares traded. Genetic Technologies lost 8.3 percent; Oncosil fell 4.2 percent; Circadian was down 3.3 percent; Ellex and Neuren shed more than two percent; with Admedus, Anteo, Benitec, Cochlear, Compumedics, Medical Developments, Nanosonics and Viralytics down more than one percent.

VIRALYTICS

Viralytics says that the final data from its 57-patient phase II trial of Cavatak for melanoma shows that eight patients had a complete response and eight had a partial response.

Viralytics said that the data was presented at the American Society of Clinical Oncology Meeting in Chicago, Illinois by lead investigator and Utah-based Huntsman Cancer Institute Prof Robert Andtbacka and the poster is available at the company's website: www.viralytics.com.

Last year, the company said that 22 patients achieved the immune-related progression-free survival endpoint, which was more than double the target of 10 patients, in the study of Cavatak, or Coxsackievirus A21, oncolytic virus immunotherapy in patients with advanced melanoma (BD: Sep 29, 2014).

Today, the company said that of the 16 of 57 patients with an overall response rate, "eight patients achieved a complete response and disappearance of their total tumor burden and the other eight achieved a partial response being at least a 30 percent reduction in the tumor burden [and] durable responses, persisting for six months or more, were seen in 21 percent of patients".

Viralytics said that durable response was the US Food and Drug Administration approved endpoint for the pivotal phase III trial of Amgen's oncolytic virus talimogene laherparepvec (T-Vec) which recently gained recommendation for approval from the FDA's Cellular, Tissue and Gene Therapies Advisory Committee and the Oncologic Drugs Advisory Committee with a 16.3 percent durable response rate.

The company said that responses had been observed in patients who had progressed on other agents such as T-Vec and the checkpoint inhibitor ipilimumab and promising anti-cancer activity was demonstrated in non-injected distant cancers, including lung and liver metastases, with a response rate of 37.5 percent recorded in individual target lesions at these sites, suggestive of Cavatak's ability to trigger an anti-tumor immune response.

Viralytics said that the one-year survival rate of 75 percent or 43 of 57 patients, with a median overall survival of 26 months was achieved "in a challenging population with advanced, intractable disease".

Dr Andtbacka said that the results "marked Cavatak as a new agent with significant promise in a range of settings, based on its performance in meeting the primary endpoint, its favorable tolerability profile and its ability to produce durable responses".

"We are encouraged by initial interesting data showing that Cavatak can reconstitute immune activity in the tumors of patients who have failed multiple other treatments suggesting a potential role in combination with other new immunotherapies," Dr Andtbacka said.

Viralytics said that biopsies from the 13-patient extension study showed that Cavatak was able to induce anti-cancer immune activity.

The company said that there was evidence that Cavatak induced key immune cells, such as cytotoxic T-lymphocytes and programmed death ligand-1 expressing cells, to infiltrate the tumor tissue including into lesions of patients that have progressed on treatment ipilimumab, pembrolizumab or talimogene laherparepvec.

Viralytics said that increases in the number of these cells were important signals of potential complementary activity in combination with important new immunotherapies such as checkpoint inhibitors.

Viralytics managing director Dr Malcolm McColl said the results were "a major milestone".

"We have demonstrated that Cavatak has strong anti-cancer activity in late-stage patients, whilst being well tolerated," Dr McColl said. "Durability of response and activity in non-injected sites are further indications of Cavatak's substantial potential."

Viralytics fell one cent or 1.6 percent to 61 cents with 2.1 million shares traded.

CIRCADIAN TECHNOLOGIES

Circadian says an Eli Lilly phase I trial has shown the licenced vascular endothelial growth factor receptor-3 (VEGFR-3) antibody IMC-3C5 is safe, tolerated with potential efficacy.
Circadian said that Eli Lilly had licenced IMC-3C5, or LY3022856, a fully-human immunoglobulin type G1 (IgG1) monoclonal antibody to be developed as a treatment for cancer and paid an annual licence fee, along with potential royalties on future product sales.
The company said that Eli Lilly presented the data at the American Society of Clinical Oncology and the dose escalation trial reached the highest planned dose of 30mg/kg and didn't reach a maximum tolerated dose.
Circadian said that the first-in-human US trial enrolled 44 patients refractory to standard therapy in two parts, a dose escalation trial of 23 patients with advanced solid tumors and an expansion cohort to evaluate IMC-3C5monotherapy at 30mg/kg in 21 patients with colorectal cancer.
The company said that weekly intravenous administration of IMC-3C5 was shown to be well-tolerated up to the highest planned dose of 30mg/kg, a maximum tolerated dose was not reached and the pharmacokinetic profile of IMC-3C5 was favorable with dose-related increases in exposure observed following weekly infusions.
Circadian said that the most common treatment emergent side effects were nausea, fatigue, vomiting and anorexia.
The company said that in the dose escalation part of the trial four of eight patients with colorectal cancer refractory to standard therapy treated at 30mg/kg "had prolonged progression free survival" of 10 to 39 weeks while in the second part of the trial the median progression free survival was 6.3 weeks.
Circadian said that biomarker analysis showed an increase in soluble VEGFR-3 levels in patient plasma samples following IMC-3C5 administration suggesting engagement with the VEGFR-3 target, while plasma VEGF-C and VEGF-D levels were not significantly changed following dosing.
The company said that IMC-3C5 blocked VEGF-C and VEGF-D activation of VEGFR-3, which inhibited blood and lymphatic vessel growth, but did not block VEGFR-2 which VEGF-C and VEGF-D also activated.
Circadian said that Eli Lilly would consider future development of IMC-3C5 in indications in which lymphatic vessel growth played a prominent role.
The abstract of the poster is at: http://abstracts.asco.org/156/AbstView_156_143954.html.
Circadian fell half a cent or 3.3 percent to 14.5 cents.

NOVOGEN

Novogen says its one-for-six rights issue and shortfall placement at 30 cents a share has raised $17,691,362 taking the total raised to $33,216,362.
In April, Novogen raised $15,525,000 in a placement of 51,750,000 shares at 30 cents a share to US institutional investors and said at that time that each placement and rights issue share would come with one attaching six-month option exercisable at 30 cents and half of one attaching five-year option exercisable at 40 cents (BD: Apr 21, 2015).
Today, Novogen said the rights issue received acceptances for a total of 56,742,571 shares of a maximum of 58,971,207 shares and the shortfall had been placed.
The company said that Lodge Partners acted as lead agent to place the shortfall shares.
Novogen executive chairman Dr Graham Kelly said it was "a great result ... [and] demonstrates the high level of support that we have in our shareholder base".
Novogen fell one cent or 3.6 percent to 27 cents with 1.9 million shares traded.

DORSAVI

Dorsavi says that a trial of its movement sensors in 112 back pain patients showed “a significant and sustained improvement in pain and functional ability”.

Dorsavi said that the 12 month study at eight sites including Melbourne’s Austin and Epworth Hospitals recruited back pain patients including 95 patients classified as chronic back pain patients.

The company said that all patients wore its Vimove sensors and had six to eight office visits over 10 weeks, with follow-up appointments held at two, three, six and 12 months.

The company said that clinicians in the intervention arm got access to the Vimove sensor data to guide care and their patients received real time feedback in weekly monitoring sessions, while clinicians and patients in the control group were blind to the data and were given no feedback by the Vimove device.

Dorsavi said that across all primary outcome measures, participants treated with the Dorsavi sensors with biofeedback showed a 35 percent to 47 percent improvement at 12 months, which were all above the threshold for clinically important difference, that is more than 30 percent above baseline scores.

The study, entitled ‘The effect of changing movement and posture using motion-sensor biofeedback, versus guidelines-based care, on the clinical outcomes of people with sub-acute or chronic low back pain-a multicentre, cluster-randomised, placebo-controlled, pilot trial’ were published online in BMC Musculoskeletal Disorders and is available at: http://www.biomedcentral.com/1471-2474/16/131.

Dorsavi said it was “the first clinical trial of its kind to investigate the effect that technology can have on the rehabilitation of low back pain”.

The company said that the trial investigated whether changing patterns of lumbo-pelvic movement and/or posture using motion sensor biofeedback, provided by Vimove, in people with low back pain would lead to reduced pain and activity limitation when compared with guidelines-based medical treatment or physiotherapy.

Dorsavi said that in the past, compared with placebo or no treatment, most non-surgical treatments for non-specific low back pain showed only small to moderate effects with one treatment showing little superiority over the other and short term treatment effects typically reduced over the subsequent year.

Dorsavi chief executive officer Dr Andrew Ronchi said that “medical adoption by health practitioners is based on having protocols supported by clinical evidence and published in peer reviewed journals”.

“We are delighted with the results of the trial and that it has now been published in a peer reviewed journal,” Dr Ronchi said.

Dorsavi was up one cent or 3.7 percent to 28 cents.

DORSAVI

Separately, Dorsavi said it had signed the UK Your Physio Plan healthcare plan to use the Vimove sensor system.

The company said that Your Physio Plan had 83 member clinics and planned to expand to more than 300 clinics over the next year.

Dorsavi said that an initial 10 Vimove devices had been licenced to Your Physio Plan and would be deployed in five of its clinics and the two companies would “work over the next three months to integrate and establish Vimove as the standard-of-care for assessing and managing back pain within those clinics”.

The company said that some of the clinics would pilot integrating Vimove into the services currently offered to National Health Service patients.

IQ3 CORP

IQ3 says it has been appointed by related party IQX Investment Services to raise $100 million as part of its IQ Series 8 Life Science Fund.
IQ3 said that the fund was “a wholesale managed fund focused on life science companies actively involved in the late discovery, or pre-clinical development, stage of the research and development of biotechnology life science compounds”.
IQ3 chief executive officer Dr George Syrmalis said it was “one of the most exciting and innovative biotech funds in Australia, as it has a focus on very early stage biotech and a preference towards privately held companies”.
IQ3 was untraded at 49 cents.

SIMAVITA

Simavita says the London-based Bunzl Outsourcing Services has signed a non-exclusive distribution agreement for the Smart Incontinence Management (SIM) system in Australia.
Simavita said that Bunzl would introduce and implement the SIM product in Australia, targeting a minimum of 70 sites operated by current Bunzl customers.
The company said that Bunzl would invest in sufficient inventory to serve current and new aged care customers and would work with Simavita to introduce SIM to new customers.
Simavita said the companies would collaborate on opportunities such as residential aged care industry tenders and both would engage in joint sales and marketing initiatives.
Simavita chief executive officer Philippa Lewis said her company was “delighted to have entered into this agreement with Bunzl Outsourcing Services, which has one of the best reputations for their provision of quality, holistic continence solutions into the Australian aged care market”.
Simavita was unchanged at 60 cents.

REPRODUCTIVE HEALTH SCIENCE

Reproductive Health says it will provide its Embryocellect pre-implantation genetic screening service to Flindersfertility from August, 2015.
Flindersfertility is a private clinic within the Adelaide-based Flinders Medical Centre public teaching hospital.
Reproductive Health was unchanged at 13.5 cents.

CELLMID

Cellmid sys it has a private label supply agreement with Taiwan healthcare business, Maywufa Company for its hair growth products.
Cellmid said the undisclosed agreement was its first private label entry into the estimated $5 billion global hair growth and anti-aging hair care market.
The company said that through wholly-owned subsidiary Advangen it would manufacture and sell FGF5 inhibitor hair growth products to Maywufa FGF5 under their brand.
Cellmid said that the contract combined the benefits of the established Taiwanese brand name and Maywufa’s extensive distribution channels, with its FGF5 inhibitor hair growth products.
The company said that Maywufa owned the largest pharmacy franchise in Taiwan with more than 200 shops and its sales network covered more than 5,000 pharmacies, general practitioners and hospitals.
Cellmid was up 0.1 cents or 4.35 percent to 2.4 cents with 16.2 million shares traded.

ANTISENSE THERAPEUTICS

Cortendo AB has become substantial in Antisense with 15,025,075 shares (8.51%) as part payment for a licence for ATL1103 for endocrinology applications, including acromegaly.
In May, Antisense said that the Trevose, Pennsylvania-based Cortendo would pay $3.7 million in cash and make a $2.5 million investment in the company, with up to $131 million in payments for development and commercialization milestones (BD: May 15, 2015).
Antisense managing director Mark Diamond told Biotech Daily at that time that the 15,025,075 share investment by Cortendo, to be held in escrow for two years, was bought at 16.75 cents a share, an 11.7 percent premium to the closing price of 15 cents when the company went into a trading halt for the announcement.
Antisense was up one cent or 9.1 percent to 12 cents.

BRAIN RESOURCE

Brain Resource says it is planning to list on the Nasdaq Global Market and change its name to Mybrainsolutions.
The cognitive testing company said that it had been consolidating all its products into one site and one brand and clients increasingly knew the company as Mybrainsolutions and it would propose the name change at the next shareholder meeting.
Brain Resource said its products were underpinned by the Brain Resource International Database and it would retain the Brain Resource name for the database.
The company said that a Nasdaq listing would provide US investors with a listing that was better aligned with their needs and had the potential to attract new investors.
Brain Resource said it had an American depositary receipts (ADRs) program in place on the over-the-counter market under the code BRRZY and it was in discussion to list the ADRs on the Nasdaq Global Market and maintain a dual listing on both the ASX and Nasdaq.
Brain Resource was untraded at 22.5 cents.

AGENIX

Last night's article on the resignation of Agenix chairman Nicholas Weston reported that among the many actions taken to restore the company, he had "resolved the OKS dispute over Thromboview".
Agenix told Biotech Daily that the dispute was not about the Thromboview technology, but related to the 2008 OKS investment for the company's failed China venture under previous chief executive officer Neil Leggett, who was later gaoled for stealing about $4 million from the company.
Mr Weston and Agenix recovered $7.6 million from the China parties.
The Monday sub-editor was confused by all the legal action and has been seconded to the Fédération Internationale de Football Association to improve her legal skills.
Agenix was untraded at 1.5 cents.