Biotech Daily

Wednesday September 21, 2016

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: BIONOMICS UP 48%, ACTINOGEN DOWN 7%**

*** BIONOMICS: 'BNC210 OUTPERFORMS LORAZEPAM FOR ANXIETY'**

*** VOLPARA EXPECTS FDA MANDATE FOR BREAST DENSITY**

*** COMPUMEDICS REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** PROTEOMICS RECEIVES $573k FEDERAL R&D TAX INCENTIVE**

*** FDA APPROVES SOMNOMED ALPHA**

*** SIRTEX AGM FOR 63k CEO 'RIGHTS', 40% DIRECTORS FEES HIKE**

*** PSIVIDA 500k SHARES, 850k OPTIONS FOR NEW CEO NANCY LURKER**

*** ORBIMED BELOW 5% IN VIRALYTICS**

*** MAYNE PHARMA APPOINTS NANCY DOLAN DIRECTOR**

*** MGC, SYDNEY UNI 2nd MEDICAL CANNABIS 'WHITE PAPER'**

MARKET REPORT

The Australian stock market was up 0.68 percent on Wednesday September 21, 2016, with the ASX200 up 36.0 points to 5,339.6 points. Thirteen of the Biotech Daily Top 40 companies were up, 15 fell, eight traded unchanged and four were untraded.

Bionomics was the best on today's trial results (see below), up 11.5 cents or 43.4 percent to 38 cents with 12.6 million shares traded.

Ellex climbed 4.3 percent; Impedimed and Universal Biosensors were up more than three percent; Benitec and Orthocell rose more than two percent; Acrux, Airxpanders, Clinuvel, Factor Therapeutics, Polynovo and Reva were up more than one percent; with CSL, Nanosonics and Resmed up by less than one percent.

Actinogen led the falls, down 0.4 cents or 6.8 percent to 5.5 cents with 506,424 shares traded. Neuren fell 5.7 percent; Admedus, IDT and Starpharma lost more than four percent; Cellmid was down three percent; Avita shed 2.2 percent; Cochlear, Genetic Signatures, Medical Developments, Mesoblast, Opthea, Osprey and Viralytics were down more than one percent; with Sirtex down 0.5 percent.

BIONOMICS

Bionomics says its 24-patient phase II trial of BNC210 for generalized anxiety disorder met its primary endpoints of change in cerebral perfusion and task-related brain activity.

Bionomics said that the secondary endpoint of suppressing anxiety-related defensive behavior in the 'joystick-operated runway task' out-performing lorazepam.

The company said that BNC210 was a first-in-class, negative allosteric modulator of the alpha-7 nicotinic acetylcholine receptor and the double-blinded, placebo and lorazepam-controlled, four-way cross-over trial was conducted in 24 patients with untreated generalized anxiety disorder at London's Kings College.

Bionomics previously said that the trial would compare BNC210 300mg or 2000mg, placebo and 1.5mg lorazepam (BD: Apr 20, 2015).

The Monthly Index of Medical Supplies and the UK Medicines & Healthcare Products Regulatory Agency say the maximum dose of lorazepam is up to 4mg a day.

Bionomics said that the study objective was to evaluate the capacity of BNC210 to engage brain systems relevant to anxiety while resting and in response to anxiety-related tasks.

The company said that the primary endpoints were change in cerebral perfusion measured by arterial spin labelling and change in task-related brain activity, specifically in the amygdala as measured by functional magnetic resonance imaging during the emotional faces task.

Bionomics said that 300mg doses of BNC210 induced statistically significant changes in cerebral perfusion ($p < 0.05$) and also significantly reduced amygdala activation in response to fearful faces during the emotional faces task ($p < 0.05$).

The company said that 1.5mg lorazepam exerted a modest suppressive effect on amygdala activation during performance of the emotional faces task ($p = 0.069$).

Bionomics said that a secondary endpoint was to determine the effect of BNC210 on defensive behavior using the joystick-operated runway task, which used a force-sensing interface to obtain an objective measure of the intensity of threat avoidance motivation.

The company said that BNC210 was associated with a significant decrease in the intensity of threat avoidance behavior with $p = 0.007$ at 300mg and $p = 0.033$ at 2,000mg, while 1.5mg lorazepam resulted in $p = 0.165$.

Bionomics principal investigator and King's College Centre for Affective Disorders director Prof Allan Young said that the "exciting phase II data herald a potential paradigm shift for the treatment of anxiety disorders".

"This patient population is poorly served with current medications and BNC210, in contrast to benzodiazepines such as lorazepam, has shown no evidence of sedation or addictive potential," Prof Young said.

Bionomics said that there was evidence that the amygdala played a major role in fear and anxiety reactions and data from the study indicated that BNC210 might exert anti-anxiety effects in patients through the suppression of amygdala activation.

King's College lecturer and developer of the joystick-operated runway task Dr Adam Perkins said that "BNC210 engages anxiety-related brain systems more effectively than lorazepam … [and] the neuro-imaging results were backed up by the behavioural findings, as BNC210 also reduced the intensity of threat avoidance behavior to a significant degree, once again out-performing lorazepam".

Bionomics chief executive officer Dr Deborah Rathjen said the data supported further development of BNC210 and gave the company "confidence that the drug has the potential to bring relief to sufferers of anxiety and trauma and stress-related disorders".

"Today's ground-breaking data also greatly strengthen the BNC210 licencing package and provide a significant boost to partnering prospects," Dr Rathjen said.

Bionomics climbed 11.5 cents or 43.4 percent to 38 cents with 12.6 million shares traded.

VOLPARA HEALTH TECHNOLOGIES

Volpara chief executive officer Dr Ralph Highnam says he hopes the US Food and Drug Administration will mandate breast density measurements in the next six months.

Dr Highnam told Biotech Daily that Volpara had the leading technology for measuring breast density, and along with its breast mammography quality control, were critically important for assessing and diagnosing breast cancer.

Dr Highnam said that the FDA's National Mammography Quality Assurance Advisory Committee met last week and was told by the FDA medical officer Dr David Lerner that the "FDA intends to propose amendments to [the Mammography Quality Standards Act] regulations … to require reporting of breast density in reports to [health care professionals] and lay summaries to patients".

Dr Lerner said that the National Mammography Quality Assurance Advisory Committee meeting in November 2011 "reached a consensus to require reporting of breast density".

Yesterday, Volpara told the ASX that it had delivered a presentation at the Committee meeting hosted by the FDA on September 15, 2016 and it was "the only provider of breast density screening to deliver a public presentation".

Dr Highnam said in yesterday's media release that the meeting was "very important as it gave us insights into how the FDA is moving with regards to quality control in mammogram screening and the need to report breast density to patients".

"It allowed us to present to the FDA and the wider Committee our new developments in these areas, namely Volpara Enterprise with its automated quality control functions," Dr Highnam said.

Today, Dr Highnam told Biotech Daily that 28 US states had laws requiring women to be told their breast density, but state law could take time to percolate down to hospitals and clinics.

"The FDA is formulating guidance on mandating all women to be told their breast density," Dr Highnam said.

Dr Highnam said that an FDA mandate would put pressure on the European regulators to also mandate breast density as a measure for accurate diagnoses of breast cancer.

"The biggest quality issue is technologist performance and that is what we have just launched," Dr Highnam said.

"No one else does it," he said "It's a big white space opportunity."

Dr Highnam said that Enterprise monitored radiation dose, breast placement, and compression so that the mammogram obtains the image without the pain.

He said that immobilization of the breast was important for tissue spread and to reduce radiation dose, but over compression caused significant pain with about 10 percent of women not returning for repeat procedures.

"The FDA wants every site to measure, monitor and improve technologist performance," Dr Highnam said.

He said that Volpara's Enterprise provided an all-in-one dashboard with very clear diagnostics and could detect over or under compression along with revenue diagnostics and clinic utilization.

Dr Highnam said that one Florida site with 11 X-ray machines was unaware that one machine was giving double the radiation to large breasted women, because it was validated at one data-point of 5.0cm, whereas Enterprise measured all data-points.

Dr Highnam said that Enterprise could detect trends of both operators and machinery.

"There are four companies with FDA clearance for breast density, but Volpara is the leader," Dr Highnam said.

He said that he expected the first sales of Enterprise "soon".

Volpara was unchanged at 50 cents.

COMPUMEDICS

Compumedics has requested a trading halt “pending an announcement in relation to a proposed capital raising”.
Trading will resume on September 23, 2016 or on an earlier announcement.
Compumedics executive chairman Dr David Burton told Biotech Daily that there had been no major capital raisings since the initial public offer in 2000.
Dr Burton said that the capital raising would fund the “scale-up of sales and marketing across the core business and new generation platforms”.
Compumedics last traded at 54.5 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has received $572,629 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Proteomics said the rebate related to development expenditure for the year to June 30, 2016 and the funds would be used “to invest heavily in its biomarker discovery program, the development and commercialisation of diabetic kidney disease test Promarkerd and new fee-for-service methods”.
Proteomics was up half a cent or 2.1 percent to 24 cents.

SOMNOMED

Somnomed says it has US Food and Drug Administration 510k approval for its instant fit Somnodent Alpha device.
Somnomed said that Alpha was the result of a two year development project and could be used by medical and dental specialists to fit an oral appliance in a matter of minutes allowing follow-up sleep tests with the device to show the level of efficacy of what it called “continuous open airways therapy” in a particular patient.
The company said that Alpha filled “the requirements of some medical specialists, hospitals or insurers who wish to test the impact of [continuous open airways therapy] before a permanent device was fitted to the patient”.
Somnomed said that patents had been lodged for Alpha and it would assist in broadening the acceptance of its continuous open airways therapy as an alternative treatment to continuous positive airways pressure.
Somnomed was up 10 cents or three percent to $3.46.

SIRTEX MEDICAL

Sirtex will vote to grant chief executive officer Gilman Wong 62,881 performance shares worth about $1.95 million and raise directors’ remuneration 40 percent to $1,400,000.
Last year, Sirtex voted to grant Mr Wong 45,930 performance rights worth about $1.5 million, with 11.9 percent opposition to the grant, and in 2014 Sirtex shareholders voted overwhelmingly to grant Mr Wong 73,000 rights, but there was opposition from 23.8 percent of the company to increase the maximum aggregate remuneration for non-executive directors by 60 percent to $1,000,000 (BD: Oct 28, 2014; Oct 27, 2015).
Today, the company said that shareholder would also vote on the remuneration report and to re-elect director Dr John Eady.
The meeting will be held at the Sofitel Sydney Wentworth hotel, Brisbane Room, 61-101 Philip Street, Sydney, on October 25, 2016 at 10am (AEDT).
Sirtex fell 15 cents or 0.5 percent to $30.95 with 196,276 shares traded.

PSIVIDA

Psivida says it will provide newly-appointed chief executive officer Nancy Lurker an option on 850,000 shares and up to 500,000 performance shares (BD: Sep 16, 2016).
Psivida said the "inducement awards" of option and shares were subject to shareholder approval and the performance shares would be based on total shareholder returns.
The company said that the option had an exercise price of $US3.63 ($A4.80) a share, which was the closing price on the Nasdaq on September 15, 2016, within 10 years and would vest in four tranches on the four anniversaries of grant and the performance shares would vest on the third anniversary of the grant.
Psivida was untraded at $4.50

VIRALYTICS

The New York-based Orbimed Advisors says 12,000,000 shareholding in Viralytics has been diluted from 5.204 percent to 4.99 percent.
Orbimed became substantial in Viralytics in December 2015 acquiring the 12,000,000 shares at 61.5 cents a share.
Viralytics fell one cent or 1.1 percent to 93 cents.

MAYNE PHARMA GROUP

Mayne Pharma says that Nancy Dolan has been appointed as a director, effective immediately.
Mayne said that Ms Dolan had more than 30 years experience in the legal and financial services sector and was previously the University of Sydney's general counsel and principal officer, a Pricewaterhousecoopers partner and a Mallesons Stephen Jacques partner.
The company said that Ms Dolan was currently the Chartered Accountants Australia and New Zealand chair of the professional conduct oversight committee.
Mayne said that Ms Dolan held a Bachelor of Laws from the Wellington, New Zealand based Victoria University a Bachelor of Arts from the Christchurch New Zealand-based University of Canterbury.
Mayne was up two cents or one percent to $2.02 with 4.3 million shares traded.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says it has developed a second medical cannabis 'white paper' with the University of Sydney Business School (BD: Mar 29, 2016).
White papers are normally issued by governments giving information or proposals on an issue, but some US businesses use a white paper as a form of marketing.
MGC said that the new white paper was titled 'Clinical Evidence for Medical Cannabis: Epilepsy, Cancer and Multiple Sclerosis' evaluating the evidence on "the efficacy of medical cannabis in treating a variety of major diseases".
The company said it provided its "expertize, contacts and know-how developed in the Israeli medical cannabis industry to the Business School's program for the white paper [which showed its] leadership in the emerging Australian medical cannabis industry".
MGC fell 0.2 cents or 4.8 percent to four cents with 3.4 million shares traded.