



Biotech Daily

Monday February 20, 2017

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: AVITA UP 5%, USCOM DOWN 8%**
- * **BIONOMICS TRIALS BNC105, KEYTRUDA FOR ADVANCED MELANOMA**
- * **IMMURON COMPLETES IMM-124E NASH RECRUITMENT**
- * **ESENSE LAB LISTS ON ASX FOR PLANT TERPENES**
- * **G MEDICAL IPO HOPES TO RAISE UP TO \$12m FOR ELECTRONIC HEALTH**
- * **NANOSONICS H1 REVENUE UP 127% TO \$37m, LOSS TO \$22m PROFIT**
- * **ACRUX H1 REVENUE DOWN 20% TO \$14m, PROFIT DOWN 35% TO \$6m**
- * **MEDICAL DEV H1 REVENUE UP 34% TO \$8m, PROFIT UP 74% TO \$410k**
- * **MEDADVISOR H1 REVENUE UP 128% TO \$1.5m, LOSS UP 85% TO \$2m**
- * **TAKEOVERS PANEL REJECTS JAMES WHEELDON INNATE APPLICATION**
- * **FUJIFILM TAKES 10% OF CYNATA**
- * **THE BOAT FUND TAKES 5% OF ITL**
- * **PETER MEURS INCREASES, DILUTED TO 17% OF DIMERIX**
- * **MGC RELEASES 210m ESCROW SHARES**
- * **SIMON ROBERTSON REPLACES BOTANIX CO SEC BRETT TUCKER**

MARKET REPORT

The Australian stock market fell 0.18 percent on Monday February 20, 2017 with the ASX200 down 10.7 points to 5,795.1 points. Twelve of the Biotech Daily Top 40 stocks were up, 16 fell, eight traded unchanged and four were untraded.

Avita was the best, up half a cent or 4.8 percent to 11 cents with 148,199 shares traded, followed by Psivida up 4.1 percent to \$2.27 with 1,275 shares traded. Clinuvel, Mesoblast, Sirtex and Viralytics were up three percent or more; Bionomics, Impedimed, Pro Medicus and Universal Biosensors rose more than two percent; Osprey and Medical Developments were up more than one percent; with Cochlear and Resmed up less than one percent.

Uscom led the falls, down two cents or 8.3 percent to 22 cents with 74,372 shares traded. Ellex, Orthocell and Pharmaxis lost five percent or more; Admedus and Opthea fell more than four percent; Anteo, Benitec, Compumedics, IDT and Prima shed more than two percent; Acrux, Neuren, Oncosil and Starpharma were down more than one percent; with CSL and Reva down by less than one percent.

BIONOMICS

Bionomics says it will begin a phase I dose-escalation trial of BNC105 in combination with Merck Inc checkpoint inhibitor Keytruda for unresponsive advanced melanoma.

Bionomics said the trial of about 30 patients would be a collaboration with the Peter MacCallum Cancer Centre and the Olivia Newton-John Cancer Wellness and Research Centre and was supported by a Victorian Government grant of \$2.25 million.

The company said that Keytruda would be provided by Merck, known as Merck Sharp and Dohme outside the US and Canada, and would be the first clinical assessment of the combination of the PD-1-inhibitor pembrolizumab, or Keytruda, with the vascular disrupting agent BNC105.

Bionomics said that Olivia Newton-John Cancer Centre medical director Prof Jonathan Cebon helped identify a strategy to improve the immunogenicity of cancer through the combination of the anti-PD-1 drug with BNC105.

Bionomics chief executive officer Dr Deborah Rathjen said that research was “poised to significantly impact melanoma through remarkable advances in systemic therapy that target the oncogenic drivers of melanoma and/or activate the host immune response by inactivating key immune checkpoints to activate T-cell mediated killing”.

“These advances have led to the median survival of patients with advanced disease being extended from a historical nine months to over two years,” Dr Rathjen said.

Bionomics said that about 1,800 Australians died every year from melanoma and it was the most common cancer in 20 to 40 year olds and unlike other cancers there had been no reduction in standardised mortality over the last two decades.

The company said that the aims of the translational research project were to prevent resistance to combined BRAF & MEK inhibition; extend the benefit of anti-PD-1 based therapies to higher proportions of patients; and improve the efficacy of immune checkpoint inhibitors in melanoma brain metastases.

Bionomics said that the trial results were expected to include objective response rate of the combination in overcoming therapeutic resistance in melanoma, overall survival, progression-free survival, duration of response to pembrolizumab and BNC105, the effect of pembrolizumab and BNC105 on the tumor micro-environment and baseline genomic and immunological predictors of the outcomes.

The company said that the dose escalation cohort would have pembrolizumab combined with BNC105 in 28 day cycles, followed by an expansion cohort of 20 patients with a minimum of eight patients required to have paired biopsies at baseline and 10 to 17 days after starting therapy.

Bionomics was up one cent or 2.7 percent to 38.5 cents.

IMMURON

Immuron says it has recruited all 120 patients in its phase II trial of IMM-124E for non-alcoholic steato-hepatitis, or fatty liver disease.

Immuron began the randomized, double-blind, placebo-controlled phase II study in 2014 and ramped-up recruitment last year increasing trial sites to 13 in the US and six in Australia (BD: Nov 27, 2014; May 25, Oct 28, 2016).

The company said it expected top line results by the end of this year.

Immuron has initiated a 40 paediatric patient trial of IMM-124E for non-alcoholic steato-hepatitis at the Atlanta, Georgia-based Emory University (BD: Feb 6, 2017).

Immuron was unchanged at 31 cents.

ESENSE-LAB

Esense says it has raised \$3.5 million in its initial public offer at 20 cents a share to develop terpenes to reconstruct essential oils including cannabis and saffron.

The Israel-based Esense listed on the ASX last week under the code ESE with Perth, Western Australia-based Otsana Capital the lead manager to the offer (BD: Dec 6, 2016).

The company's chairman is Otsana Capital director Dr Brendan de Kauwe, who told Biotech Daily that terpenes were molecules that provided health benefit to plants and by reconstructing them Esense could produce any essential oil from the target plant.

Esense was up half a cent 1.9 percent to 27 cents.

G (GEVA) MEDICAL INNOVATIONS

G Medical says it hopes to raise up to \$12 million at 20 cents a share to list on the ASX and commercialize its mobile telephone electronic health devices.

The Perth-based G Medical said the initial public offer would close on March 8, 2017 and it expected to list on the ASX under the code GMV shortly afterwards.

The company said it had completed clinical trials of its technology, which included a mobile telephone cover for providing data as well as a "vital signs monitor system" which could provide electrocardiograms, respiration rate, oxygen saturation and temperature measures, with next generation models measuring blood pressure, blood glucose, uric acid, cholesterol and haemoglobin.

G Medical said it expected Conformité Européenne (CE) mark approval by July 2017 and US Food and Drug Administration approval by the end of the year, with a memorandum of understanding with Winola Lake for US distribution and a term sheet with Guangzhou Sino-Israel Bio-Industry Investment Fund for China.

G Medical said its management team was led by executive director Dr Yacov Geva the chairman was Dr Kenneth Melani, with directors including Guangzhou Israel Biotech Fund chairman Dr Shuki Gleitman and Otsana Capital director Dr Brendan de Kauwe.

The prospectus is expected to be posted on the www.akela.vc website shortly.

NANOSONICS

Nanosonics says that revenue for the six months to December 31, 2016, was up 127.4 percent to \$37,357,000, taking last year's loss to a \$21,985,000 net profit after tax.

Nanosonics said that sales of its Trophon EPR ultrasound probe cleaning system increased by 132 percent to \$36,120,000 for the six months to December 31, 2016 compared to the prior corresponding period and up 33 percent on the previous six months "mainly due to higher sales in North America where the installed base of ... increased by over 2,000 units" and all regions contributing to growth.

Nanosonics said that preparations for further geographical expansion continued with distribution negotiations taking place in Japan and the Middle East.

The company said that research and development activities associated with its product portfolio expansion and multi-generational Trophon program were progressing well with increased investment made in the six months to December 31, 2016.

Nanosonics said the diluted loss per share of 1.20 cents for the six months to December 31, 2015, turned to diluted earnings per share of 7.30 cents for the six months to December 31, 2016, with net tangible assets per share up 83.7 percent to 27.11 cents.

The company said it had cash and cash equivalents of \$56,873,000 at December 31, 2016, compared to 42,628,000 at December 31, 2015.

Nanosonics was unchanged at \$2.80 with 637,310 shares traded.

ACRUX

AcruX says that revenue for the six months to December 31, 2016 fell 20.4 percent to \$14,328,000 taking net profit after tax down 35.1 percent to \$6,322,000.

AcruX said that for the six months to December 31, 2016 sales revenue from its Axiron testosterone replacement by Eli Lilly was \$US78.9 million compared to \$US83.0 million in the previous corresponding period.

The company said that Axiron's US volume market share was steady at 14.4 percent, but royalty revenue decreased 10.5 percent to \$13.6 million, with no milestone revenue in the six month period compared to the \$US2.0 million received from Gedeon Richter for Lenzetto launches in Europe during the prior period.

AcruX said that operating expenditure increased 12.2 percent to \$5.3 million, primarily investment in research and development associated with the company's growth strategy to commercialize topical generics.

The company said that no dividend would be paid for six months to December 31, 2015.

AcruX said that diluted earnings per share fell 33.3 percent from 6.0 cents in the previous corresponding period to 4.0 cents for the six months to December 31, 2016, with net tangible asset backing per share up 46.2 percent to 19 cents.

The company said it held cash and cash equivalents of \$31,718,000 at December 31, 2016 compared to \$21,539,000 at December 31, 2015.

AcruX fell half a cent or 1.6 percent to 30 cents.

MEDICAL DEVELOPMENTS

Medical Developments says revenue for the six months to December 31, 2016, was up 34.4 percent to \$8,054,000 with net profit after tax up 73.7 percent to \$410,000.

Medical Developments said that revenue from medical devices climbed 103.7 percent to \$2,842,000, revenue from the Pentrox inhaled methoxyflurane analgesic was up 13.6 percent to \$4,918,000 and veterinary product revenue rose up 10.9 percent to \$294,000.

The company said that revenue from the sale of Pentrox to Australian ambulance services fell 15 percent compared to the same period last year.

Medical Developments said that In November and December 2015 it sold large amounts of stock to the ambulance services to ensure supply during the closure of the factory and the move of offices from Springvale to Scoresby, which created an unusual timing anomaly.

The company said that in the next six months it expected to complete its manufacturing facility and research and development laboratories, conclude distribution partnerships for Pentrox and respiratory devices, begin work on other analgesic and anaesthetic products, continue its clinical program including new drug application to the US Food and Drug Administration.

Medical Developments said it had employed an additional 26 staff to cope with the on-going registration activity and planned market launches in the next 18 months.

Medical Developments declared a two cent per share dividend for the half year to December 31, 2016 for record holders at March 6, to be paid on April 10, 2017.

The company said that diluted earnings per share climbed 73.2 percent to 0.71 cents at December 31, 2016 compared to 0.41 cents for the previous period, with tangible asset per share down to negative 0.2 cents.

Medical Developments said that cash and cash equivalents at December 31, 2016 was \$5,525,000 compared to \$9,552,000 at December 31, 2015.

Medical Developments was up six cents or 1.15 percent to \$5.30.

MEDADVISOR

Medadvisor says that revenue for the six months to December 31, 2016, was up 127.8 percent to \$1,548,000 with net loss after tax up 84.5 percent to \$2,043,639.

Medadvisor said that revenue was from sales of its internet-based system ensuring that customers' prescriptions were filled correctly, with users increasing 470 percent to 630,000 users compared to the six months to December 31, 2015, driven by its patient engagement programs and subscription revenue driven by pharmacy subscriptions.

Medadvisor said that diluted loss per share was constant at 0.26 cents for the six months to December 31, 2016, with net tangible assets per share down 13.5 percent to 0.5296 cents.

The company said it had cash and cash equivalents of \$5,927,087 at December 31, 2016, compared to \$4,680,479 at December 31, 2015.

Medadvisor fell 0.1 cents or 2.9 percent to 3.4 cents.

INNATE IMMUNOTHERAPEUTICS

The Takeovers Panel says it has "declined to conduct proceedings on an application ... from James Wheeldon in relation to the affairs of Innate Immunotherapeutics".

Last week, Takeovers Panel director Allan Bulman said that Mr Wheeldon's application said that Innate director Chris Collins was the largest shareholder with a holding of about 17 percent and Mr Wheeldon submitted, "based on publicly available information, there is an available inference that Mr Collins may be associated with family members and other shareholders and may have obtained effective control of Innate Immunotherapeutics in contravention of section 606 of the Corporations Act 2001" (BD: Feb 15, 2017).

Mr Bulman said last week that Mr Wheeldon "seeks an interim order to the effect that Mr Collins disclose to the ASX information including details of any associations he has with any other Innate Immunotherapeutics shareholders".

Today, Mr Bulman said that Mr Wheeldon "submitted, among other things, that there is an available inference that Mr Collins, a director and shareholder of Innate, may be associated with family members and other shareholders".

"The Panel considered that the applicant did not provide sufficient material to justify the Panel making further enquiries and, in the circumstances of the matter, there was no reasonable prospect that it would make a declaration of unacceptable circumstances," Mr Bulman said.

"Accordingly, the Panel declined to conduct proceedings," Mr Bulman said.

Mr Bulman said that the Panel would publish its reasons for the decision in due course on its website www.takeovers.gov.au.

Innate fell 1.5 cents or 1.9 percent to 78 cents.

CYNATA THERAPEUTICS

The Tokyo, Japan-Based Fujifilm Corp says it has become a substantial shareholder in Cynata with 8,088,403 shares or 10.01 percent.

The substantial shareholder notice said that Fujifilm acquired the shares on January 25, 2017 for \$3,972,458 or 49.1 cents a share.

Cynata fell one cent or 1.6 percent to 60.5 cents.

[ITL](#)

The Sydney-based The Boat Fund Investment Management says it has become a substantial shareholder in ITL with 4,850,000 shares or 5.06 percent.

The substantial shareholder notice said that TBF acquired the shares on-market between January 27 and February 20, 2017 at prices ranging from 37.5 cents to 50 cents a share. ITL was up 3.5 cents or 7.1 percent to 53 cents.

[DIMERIX](#)

Peter Meurs says he has increased his shareholding in Dimerix but has been diluted from 290,660,567 shares (20.78%) to 317,084,255 shares (17.33%).

The substantial shareholder said the increase in shareholding was through the conversion of performance shares, with the holding diluted in a placement.

Dimerix was untraded at 0.8 cents.

[MGC \(MEDICAL GRADE CANNABIS\) PHARMA](#)

MGC says that 140,000,000 shares and 70,000,000 performance shares held in ASX escrow were released on February 15, 2017.

MGC said that it had 842,613,155 ordinary shares on issue, along with 13,000,000 shares in voluntary escrow and 91,818,380 options exercisable at 6.5 cents each by June 30, 2019.

MGC was unchanged at 3.8 cents.

[BOTANIX PHARMACEUTICALS](#)

Botanix says that Simon Robertson has replaced Brett Tucker as company secretary effective from February 17, 2017.

Botanix said that Mr Robertson was the company secretary for a number of publicly listed companies and had experience in corporate finance, accounting and administration, capital raisings and ASX compliance and regulatory requirements.

The company said that Mr Robertson held a Bachelor of Business from Curtin University in Western Australia and a Masters of Applied Finance from Macquarie University in New South Wales.

Botanix fell 0.1 cents or 2.2 percent to 4.5 cents.