



Biotech Daily

Wednesday May 24, 2017

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: DIMERIX UP 14%, IMPEDIMED DOWN 4%**
- * **SIRTEX CEO ANDREW MCLEAN STARTS ON \$825k, \$500k 'TRANSITION FEE'**
- * **GI DYNAMICS META-ANALYSIS: WEIGHT LOSS, HBA1C DOWN**
- * **JAPAN PATENT FOR REGENEUS PROGENZA STEM CELLS**
- * **NOXOPHARM NOX66 RARE CANCERS COMPASSIONATE USE, TRIAL**
- * **AQSITANIA USES USCOM TSPIRO FOR LUNG TRANSPLANT MONITORING**
- * **STEVE LYDEAMORE TO REPLACE BIONOMICS CFO MELANIE YOUNG**
- * **BRAIN APPOINTS EMIL VASILEV FINANCE, OPERATIONS DIRECTOR**

MARKET REPORT

The Australian stock market edged up 0.15 percent on Wednesday May 24, 2017 with the ASX200 up 8.8 points to 5,769.0 points.

Eleven of the Biotech Daily Top 40 stocks were up, 14 fell, 14 traded unchanged and one was untraded. All three Big Caps were up.

Yesterday's 30 percent worst, Dimerix, was the best, up 0.1 cents or 14.3 percent to 0.8 cents with 8.6 million shares traded.

Cellmid and Opthea climbed more than seven percent; Benitec was up 6.9 percent; Atcor improved five percent; Medical Developments was up 3.65 percent; Avita, Uscom and Viralytics rose more than two percent; Compumedics, Cochlear, CSL and Factor Therapeutics were up more than one percent; with Resmed up 0.8 percent.

Yesterday's 3.7 percent best, Impedimed, led the falls, down three cents or 4.3 percent to 67 cents with 739,542 shares traded, followed by ITL down 4.1 percent to 59 cents with 225,153 shares traded.

Admedus and Universal Biosensors lost more than three percent; Psivida and Starpharma shed more than two percent; Actinogen, Bionomics, Mesoblast, Neuren, Osprey, Pharmaxis and Sirtex were down more than one percent; with Clinuvel down 0.3 percent.

SIRTEX MEDICAL

Sirtex says it has appointed Andrew McLean as chief executive officer, starting on \$825,000 a year with a \$500,000 'transitional arrangement' from June 5, 2017.

Sirtex said that Mr McLean would also be entitled to a cash short term incentive of 50 percent of his base salary, subject to individual and company performance and a further 25 percent of base salary as a long term incentive.

The company said Mr McLean had more than 20 years experience, most recently as Synergy Health PLC's Applied Sterilisation Technologies and Laboratories chief executive officer and the Mentor, Ohio-based Steris Corp's head of corporate strategy and previously worked for Pfizer and Becton Dickinson in Asia and Australia.

Sirtex said that Mr McLean held a Bachelor of Economics from Macquarie University and a Master of Business Administration from the Macquarie Graduate School of Management.

Sirtex chairman Richard Hill said the board thanked interim chief executive officer Nigel Lange, who would move to chief commercial officer.

Mr Lange was appointed interim chief executive officer following the dismissal of long-serving chief executive officer Gilman Wong in relation to share trading and a lower than expected rate of SIR-Spheres dose sales (BD: Dec 15, 19, 2016; Jan 22, 2017).

Sirtex fell 17 cents or 1.4 percent to \$11.81 with 486,750 shares traded.

GI DYNAMICS

GI Dynamics says a meta-analysis of up to 431 patients in 14 separate studies shows the Endobarrier duodenal-jejunal bypass liner reduces weight and blood sugar levels.

Posted at the time of the company's annual general meeting yesterday morning, GI Dynamics said the market sensitive data was presented at the Digestive Disease Week meeting in Chicago on May 8, 2017.

The company said that the study, entitled 'The effect of the duodenal-jejunal bypass liner on glycaemic control in type-2 diabetic patients with obesity: a meta-analysis with secondary analysis on weight loss and hormonal changes' was presented by the Harvard Medical School's Dr Pichamol Jirapinyo.

GI Dynamics said that the Endobarrier induced "significant weight loss and positively affects certain digestive hormones".

The study showed that the mean HbA1c blood sugar level was reduced by 1.3% at explant, with data from 99 patients in two studies showing a 1.0 percent mean reduction six months after removal of the Endobarrier.

GI Dynamics said the total body weight loss for 395 patients in 10 trials was 14 percent.

GI Dynamics chief executive officer Scott Schorer said that weight loss at the time of explant was "clinically significant ... [and] this analysis further reinforces the unique method of treatment and highly differentiated clinical treatment effect of Endobarrier".

The company said that in the earlier studies Endobarrier was implanted for six months while later studies extended the duration to 12 months.

GI Dynamics said that a subgroup analysis of four randomized controlled trials with 123 patients saw a decrease in HbA1c by 0.9 percent compared to controls.

The company said that the meta-analysis of five studies with 84 patients showed a significant decrease in glucose-dependent insulinotropic peptide at 7.8 months.

GI Dynamics said the meta-analysis showed 16 serious adverse events with the most common including abdominal pain, nausea and vomiting.

The company said that "no hepatic abscesses were found in the published studies".

GI Dynamics was up half a cent or 9.1 percent to six cents.

REGENEUS

Regeneus says the Japan Patent Office has granted a patent covering the composition, manufacture and use of its Progenza stem cell technology.

Regeneus said the patent, entitled 'Therapeutics using cells and cell secretions' would provide coverage in Japan until 2032 and protected the allogeneic, or off-the-shelf, fat-derived stem cell technology for osteoarthritis and other inflammatory conditions for The company said that corresponding patents had been granted in Australia and New Zealand and were being pursued in other territories including the US and Europe.

Regeneus said that the rights to Progenza for all clinical applications in Japan had been licenced to its joint venture with the Tokyo-based AGC Asahi Glass, Regeneus Japan Inc, with Japan manufacturing rights licenced exclusively to AGC and discussions underway with potential licencees for specific indications in Japan.

Regeneus chief executive officer John Martin said "the timing for the issue of this patent in Japan couldn't be better".

"It comes on the back of having announced positive data from our phase I Step trial of Progenza for knee osteoarthritis," Mr Martin said (BD: May 22, 2017).

"The combination of positive clinical data, an issued patent and our strategic collaboration with AGC, will put us in a strong position to convert our clinical partnering discussions into good commercial outcomes," Mr Martin said.

The company said it had 56 patents or patent applications across 14 patent families, providing "a substantial competitive advantage for the company's product pipeline".

Regeneus was up half a cent or 3.7 percent to 14 cents.

NOXOPHARM

Noxopharm says it will take NOX66 from Australian compassionate use for rare cancers to a clinical trial.

Noxopharm did not say where NOX66 was available under a compassionate use scheme.

The company said that rare cancers were those with an incidence of fewer than six patients per 100,000 people per year and included 186 different cancers.

Noxopharm said that despite their very low incidence, collectively rare cancers account for about up to 25 percent of cancer diagnoses, but about 40 percent of cancer deaths.

The company said that rare cancers received "very little research funding, rarely are the subject of clinical studies, and receive less than 15 percent funding of treatment through the Australian Government's Pharmaceutical Benefits Scheme".

Noxopharm clinical development and medical affairs director Ian Minns said that for the past six months, the company had made NOX66 available "on a limited compassionate use basis to patients including those with rare cancers who have exhausted standard treatment options and who, because of their cancer's rarity, would otherwise have little access to clinical trials".

"We now have decided to put this informal use of NOX66 onto a formal clinical trial footing," Mr Minns said.

Noxopharm chief executive officer Dr Graham Kelly said it was "uncommon for a biotech company to make an experimental drug available on a compassionate use basis in the early stages of the drug's development".

"Our confidence in both the safety of NOX66 and its potential clinical benefit are the key reasons that we have been prepared to do so," Dr Kelly said.

Noxopharm said that the study would be conducted at sites in Australia and New Zealand.

Noxopharm was up one cent or 2.6 percent to 39 cents.

USCOM

Uscom says Aqsitania SAS will use its Spirosonic telemetric pulmonary function devices to monitor and improve management of lung transplant patients.

Uscom said that the Spirosonic Tspiro devices were “advanced, multi-path, ultrasonic spirometers that connect wirelessly to personal communication devices and ultimately web-based software applications to monitor and analyze respiratory function [for] cost-effective home-care monitoring”.

The company said that lung transplantation was expensive and required on-going pulmonary functional monitoring and the Tspiro spirometers provided “practice-leading pulmonary function measurements”.

Uscom said that the Talence, Bordeaux-based Aqsitania specialized in electronic health applications of advanced signal analysis and modelling particularly for respiratory function and development of personal respiratory profiles and the lung transplantation project was supported by European Union funding.

The company said Aqsitania had bought about 100 Tspiro devices for the pilot project, with several hundred devices expected for the second phase of the project.

Uscom said the Tspiro platform was being evaluated by telemetric asthma and chronic obstructive pulmonary disease companies developing cloud based monitoring and diagnosis software and analytics.

The company said that Tspiro devices were approved in Europe and were being submitted for US and China approval.

Uscom was up half a cent or 2.7 percent to 19 cents.

BIONOMICS

Bionomics says it has appointed Steve Lydeamore as its chief financial officer, commencing in August 2017, replacing Melanie Young.

Bionomics said that group financial controller and former chief financial officer Stephen Birrell had been appointed interim-chief financial officer.

The company said that Mr Lydeamore was an accountant with 25 years’ international pharmaceutical experience and had worked in finance for FH Faulding & Co in Australia for 10 years, followed by four years in the US at Mayne Pharma.

Bionomics said that most recently Mr Lydeamore worked for Canada’s Apotex as the head of Apobiologix which was developing of bio-similar oncology treatments.

The company said that Mr Lydeamore held a Bachelor of Business from Deakin University and a Master of Business Administration from the Royal Melbourne Institute of Technology.

Bionomics fell half a cent or 1.4 percent to 35 cents

BRAIN RESOURCE

Brain Resource says it has appointed Emil Vasilev as director of finance and operations.

Brain said that Mr Vasilev had transactional and operational experience in the technology, private equity and investment banking sectors and previously worked as an investment banker at London’s Barclays Bank and as an investor at New York’s Corsair Capital.

Brain was up 0.1 cents or 1.4 percent to 7.1 cents.