



Biotech Daily

Monday September 25, 2017

Daily news on ASX-listed biotechnology companies

- * **ASX FLAT, BIOTECH DOWN: NEUREN UP 16%, OPTHEA DOWN 9%**
- * **MEDICAL DEVELOPMENTS: 'PENTHROX FOR UK AMBULANCE'**
- * **POLYNOVO PLACEMENT RAISES \$7m, SHARE PLAN**
- * **SIENNA: AXLAB BLADDER TEST DISTRIBUTOR FOR DENMARK, SWEDEN**
- * **NOVOGEN, FDA MEETING - GDC-0084 BRAIN CANCER TRIAL ON-TRACK**
- * **GI DYNAMICS: 'ENDOBARRIER EQUALS GASTRIC PPLICATION'**
- * **ONCOSIL RECEIVES \$2.9m FEDERAL R&D TAX INCENTIVE**
- * **NOXOPHARM, DIRECTOR DR IAN DIXON SPIN OUT NYRADA**
- * **FMR TAKES 7% OF NANOSONICS**
- * **PENGANA (HUNTER HALL) REDUCES TO 11% IN AVITA**
- * **NEUROTECH REQUESTS 'MENTE AUSTISM TRIAL UPDATE'**
- * **MACH7 CEO MICHAEL JACKMAN APPOINTED M-D**
- * **AUSBIOTECH LAUNCHES 'ROADMAP TO A SUCCESSFUL IPO'**

MARKET REPORT

The Australian stock market edged up 0.03 percent on Monday September 25, 2017 with the ASX200 up 1.6 points to 5,683.7 points. Twelve of the Biotech Daily Top 40 stocks were up, 16 fell, nine traded unchanged and three were untraded.

Neuren was the best on no news, up one cent or 15.9 percent to 7.3 cents with 7.4 million shares traded. Benitec climbed eight percent; Uscom was up 6.1 percent; Cellmid was up 4.35 percent; Avita and Viralytics rose more than three percent; Living Cell and Mesoblast were up more than two percent; Admedus, Cochlear, Nanosonics and Universal Biosensors rose more than one percent; with Clinuvel and CSL up less than one percent.

Opthea led the falls, down 6.5 cents or 8.6 percent to 69 cents with 130,397 shares traded. Polynovo lost 5.3 percent; Orthocell fell 4.7 percent; Acrux, Airxanders, Cyclopharm, Starpharma and Reva were down more than three percent; Compumedics, ITL and Psivida shed more than two percent; Bionomics and Factor Therapeutics were down more than one percent; with Medical Developments, Pro Medicus, Resmed and Sirtex down by less than one percent.

MEDICAL DEVELOPMENTS

Medical Developments says the Royal Colleges Ambulance Liaison Committee has included its Pentrox in ambulance pain management clinical practice guidelines. Medical Developments provided a copy of an article from London's 'Ambulance Today' saying that the Committee guidelines recommended the use of the Pentrox methoxyflurane inhaled analgesic for adults with injuries causing moderate to severe pain. The article quoted a member of the Committee Dr Bob Winter saying that "the inclusion of Pentrox for moderate to severe pain management provides a useful treatment option for improved patient care in an emergency setting".

The article said that the East of England Ambulance Service was in the process of adopting Pentrox.

Medical Developments chief executive officer John Sharman told Biotech Daily that his company and Galen had been "waiting on the formal adoption of Pentrox by the Joint Royal Colleges Ambulance Liaison Committee since the beginning of 2017 and we are delighted it has finally arrived".

"There are currently six separate ambulance trusts in the UK which have commenced formal assessments for the adoption of Pentrox," Mr Sharman said.

"Now that Pentrox has been listed for use by JRCALC, [our] expectation is that Pentrox will be used by every ambulance service in the UK," Mr Sharman said.

Medical Developments fell four cents or 0.8 percent to \$5.00.

POLYNOVO

Polynovo says it has raised \$7.0 million in a placement at 27 cents a share and will offer a share plan for an undisclosed amount of further funds.

Polynovo said the proceeds would expand the sales and support infrastructure in the US and other markets, accelerate the research and development program to support breast and hernia applications of its Novosorb bio-resorbable material, as well as to support a possible licence agreement for a drug elution pellet and general working capital.

The company said the record date for the share plan was September 22, it would open on October 2 and close on October 20, 2017, with shares available in lots up to \$15,000.

Polynovo said that Kidder Williams was the financial adviser and Baillieu Holst was the lead manager to the placement.

Kidder Williams principal David Williams is the chairman of Polynovo.

Polynovo fell 1.5 cents or 5.3 percent to 27 cents with 2.3 million shares traded.

SIENNA CANCER DIAGNOSTICS

Sienna says it has appointed the Vedbæk, Denmark-based Axlabs AS as the exclusive distributor for its adjunct bladder cancer test in Denmark and Sweden.

Sienna said it was the first distribution agreement since it listed on the ASX and would "broaden and accelerate the global roll-out of its in-vitro diagnostic test".

The company said Axlabs would sell the product to pathology laboratories, where it will be used as an adjunct to urine cytology to assist pathologists and urologists in their diagnosis of bladder cancer.

Sienna chief executive officer Matthew Hoskin said the company would work with Axlabs to train their staff, establish inventory and supply logistics and assist them in establishing an initial reference laboratory within the territory.

Sienna was up half a cent or 3.6 percent to 14.5 cents.

NOVOGEN

Novogen says that following a meeting with the US Food and Drug Administration it is on-schedule to start a phase II GDC-0084 for glioblastoma multiforme trial this year.

Novogen said it had a type B meeting with FDA on September 21, 2017 at the Centre for Drug Evaluation and Research in Maryland to discuss the development plan for GDC-0084 in adult patients with glioblastoma multiforme.

The company said that it was “confident following the meeting that the study remains on schedule to commence by the end of calendar 2017 and that the key design features remain substantially unchanged”.

Novogen said that independently of FDA feedback it had elected to include a lead-in component in the phase II study that would optimize dosing.

The company said the Genentech phase I trial was in high-grade gliomas and all patients had progressed during or after treatment with at least one prior line of therapy.

Novogen said it intended to conduct the phase II study only in patients with glioblastoma in a first-line setting, so there might be potential to improve the dosing regimen.

The company said the staged approach would help to de-risk the overall phase II program and provide an initial data read-out about 12 to 15 months after the start.

Novogen said that it had a letter of intent with Chiltern Oncology to act as its contract research organization.

Novogen was unchanged at four cents.

GI DYNAMICS

GI Dynamics says its Endobarrier duodenal sleeve is as effective as “gastric plication” surgical stomach reduction for obesity and type 2 diabetes at 10 months post-implant.

GI Dynamics said that a 40-patient trial performed by the Prague, Czech republic-based Institute for Clinical and Experimental Medications reaffirmed previous results comparing the Endobarrier to other procedures for up to 12 months (BD: May 20, 2015).

The company said the Institute’s Dr Anna Cinkajzlova presented data entitled ‘Circulating Lipopolysaccharide and Gut Permeability in Obese Subjects with Type 2 Diabetes: The Influence of Surgical and Endoscopic Interventions’ at the Lisbon, Portugal meeting of the European Association for the Study of Diabetes, September 11 to 15, 2017.

GI Dynamics said the trial divided 30 people with type 2 diabetes and obesity into 15 receiving the Endobarrier, 15 undergoing surgical plication, with 10 healthy controls.

The company said the gastric plication patients were measured at baseline, one month and six-months post-treatment, while the Endobarrier was measured at baseline, one month and at 10 months when the Endobarrier was removed.

GI Dynamics said the analysis assessed circulatory levels of lipopolysaccharide binding protein, fatty acid binding protein 2 and sCD14 following assigned weight-reducing treatments combined with quantification of adipose tissue macrophages and compared the clinical outcomes across multiple health metrics and biomarkers.

The company said the data indicated similar outcomes with the two techniques including reduction of systemic inflammation and a significant reduction of subcutaneous adipose, or fat, tissue inflammation.

GI Dynamics said the study showed little involvement in change of circulating lipopolysaccharide levels or gut leakage in either procedure.

“On a basic science and mechanistic basis, both treatments ... substantially improved metabolic parameters and were associated with reduction in systemic inflammation as well as adipose tissue inflammation,” Dr Cinkajzlova said.

GI Dynamics was untraded at 4.9 cents.

ONCOSIL MEDICAL

Oncosil says it has received \$2,884,658 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Oncosil said that the cash rebate was related to expenditure on eligible Australian and international research and development activities conducted in the year to June 30, 2017. Oncosil was unchanged at 10 cents.

NOXOPHARM

Noxopharm says it has formed subsidiary Nyrada Inc to develop pre-clinical, non-oncology drug intellectual property.

Noxopharm said that Nyrada was Delaware-registered, based in New York and would develop NYX-104 and NYX-105 and an unnamed molecule for four main indications.

The company said it would call an extraordinary general meeting for shareholders to approve the venture on November 9, 2017.

Noxopharm said that NYX-104 was designed to inhibit a secondary disease of the central nervous system known as excito-toxicity, or the death of nerve cells as a secondary event following injury to the brain and spinal cord associated with stroke, trauma, repeat concussion or severe epilepsy and said that progressive brain shrinkage associated with sporting concussive injuries was an example of excito-toxicity.

The company said NYX-105 was designed to inhibit thromboxanes in inflammation, which were implicated in a range of diseases including peripheral neuropathies, or the loss of function of peripheral nerves, inflammatory bowel disease and ulcerative colitis.

The company said its intellectual property in both compounds related to the application of proprietary drug delivery technology designed to improve drug access to diseased tissues.

Noxopharm said the unnamed molecule was owned by private drug development company, Cardio Therapeutics Pty Ltd, owned by Altnia Holdings Pty Ltd as trustee for the I Dixon Family Trust, with Altnia controlled by Noxopharm director Dr Ian Dixon.

The company said that the small molecule drug was designed to lower low density lipoprotein cholesterol levels through inhibition of the PCSK9 protein, potentially offering significant advantages compared to current therapies.

Noxopharm said it and Altnia co-owned Nyrada.

The company said that NYX-104 and NYX-105 had been transferred to two Noxopharm subsidiaries known as Norbio No 1 Pty Ltd and Norbio No 2 Pty Ltd, respectively it had a conditional share sale and subscription agreement with Nyrada in which Norbio No 1 and Norbio No 2 would go to Nyrada for 6,669 Nyrada shares.

The company said that Nyrada had a share sale and subscription agreement with Altnia, in which Cardio would be sold to Nyrada for 3,329 Nyrada shares.

Noxopharm said that on completion it would own 66.7 percent of Nyrada and Altnia would hold 33.3 percent.

Noxopharm was up half a cent or 1.5 percent to 34.5 cents.

NANOSONICS

Fidelity Management & Research (FMR) says it has increased its shareholding in Nanosonics from 17,974,691 shares (6.04%) to 21,063,360 shares (7.04%).

FMR said it acquired the 3,088,669 shares between and September 8 and 20, 2017, at prices from \$2.60 to \$2.70.

Nanosonics was up five cents or 1.9 percent to \$2.63 with 1.4 million shares traded.

AVITA MEDICAL

The Sydney-based Pengana Capital says it has reduced its holding in Avita from 82,041,700 shares (12.19%) to 73,336,277 shares (10.89%).

The Pengana notice said the Avita shares were held by Pengana Capital, Pengana Capital Group, Hunter Hall Investment Management and Hunter Hall Global Vlaue. Pengana said it sold shares between July 3 and August 30, 2017, with the single largest sale 329,027 shares for \$26,212 or 8.0 cents a share.

Avita was up 0.2 cents or 3.5 percent to 5.9 cents with 1.8 million shares traded.

NEUROTECH INTERNATIONAL

The Malta-based Neurotech has requested a trading halt “pending the announcement ... of a progress update on the independent US clinical trial of Mente Autism”.

Trading will resume on September 27, 2017 or on an earlier announcement.

Neurotech last traded at 16.5 cents.

MACH7 TECHNOLOGIES

Mach7 Technologies says chief executive officer Michael Jackman has been appointed as managing-director, effective today September 25, 2017.

Mach7 was up half a cent or three percent to 17 cents.

AUSBIOTECH

Ausbiotech says it launched a ‘Roadmap to a successful IPO for life sciences companies’ at the ASX in Sydney last week, with “a second launch” in Melbourne, on October 3, 2017. Ausbiotech said the Roadmap was developed with the ASX, Swiss accountancy company KPMG (Klynveld Peat Marwick Goerdeler), Sydney law firm Dibbsbarker and investor relations company WE Buchan.

The industry organization said the Roadmap was one of the four main components of the Federal Government funded MTP Connect ‘Comprehensive Global Investment Program for the Australian Life Sciences Sector’ and would provide life sciences companies with independent, non-proprietary information about becoming an ASX-listed company.

The organization said that the Roadmap would be accompanied by nationwide seminars next year, to help life sciences companies decide whether an initial public offer was a suitable option and to “raise awareness, educate and inform companies about what they need to consider so that investors will find them attractive”.

Ausbiotech said the Roadmap was one of three publications to be produced under the Global Investment Program and said the consortium was developing a Guide to Life Sciences Investing aimed at new life sciences investors and a Pitching to Investors Masterclass aimed at companies and researchers looking to commercialize their research. Ausbiotech said that chief executive officer Glenn Cross KPMG partner Alan Garcia and ASX listings manager James Gerraty would speak at the Melbourne event.

Ausbiotech said the free, October 3 event would begin with registration from 5.30pm for a 5.50pm start at KPMG, 727 Collins Street, Docklands, with more information available at:

<https://ausbiotech.eventsair.com/roadmap-to-ipo/registration/Site/Register>.