



Biotech Daily

Friday November 13, 2015

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: LIVING CELL UP 22%; PRO MEDICUS DOWN 6%**
- * **AIRXPANDERS CHANGES FDA PROCESS TO DE NOVO, 30-DAY DELAY**
- * **MEDICAL AUSTRALIA: 'NO DEAL YET FOR MEDIVET BUSINESS'**
- * **NUSEP \$200k FORMER M-D PRAKASH PATEL SETTLEMENT**
- * **LIVING CELL 40% REMUNERATION 1st STRIKE, 3m OPTIONS WITHDRAWN**
- * **UP TO 34% OF BIOTA OPPOSE DIRECTOR RUSSELL PLUM, AGAIN**
- * **PRANA AGM 17% REMUNERATION REPORT DISSENT**
- * **SIMAVITA DIRECTORS POOL INCREASE AGM**
- * **BIONOMICS, MERCK NEUROSCIENCE SYMPOSIUM ON MONDAY**

MARKET REPORT

The Australian stock market fell 1.45 percent on Friday November 13, 2015 with the ASX200 down 74.4 points to 5,051.3 points.

Eleven of the Biotech Daily Top 40 stocks were up, 21 fell, six traded unchanged and two were untraded. All three Big Caps fell.

Living Cell was the best, up one cent or 22.2 percent to 5.5 cents with 861,220 shares traded. Genetic Technologies climbed 8.7 percent; Universal Biosensors was up 4.9 percent; Cellmid and Polynovo were up more than three percent; Tissue Therapies and Uscom rose more than two percent; Admedus, Antisense and Circadian were up more than one percent; with Acrux up 0.65 percent.

Pro Medicus led the falls for the second day in a row, down 20 cents or 5.95 percent to \$3.16, with 235,480 shares traded.

Benitec lost five percent; Prana fell 4.35 percent; Actinogen, Ellex, IDT, Osprey and Reva were down more than three percent; Atcor, Medical Developments, Pharmaxis, Orthocell and Resmed shed more than two percent; Anteo, Bionomics, Clinuvel, Cochlear, Compumedics, CSL and Neuren were down one percent or more; with Psivida, Sirtex, Starpharma and Viralytics down by less than one percent.

AIRXPANDERS

Airxpanders says the US Food and Drug Administration has advised it to change its 510(k) submission to a de novo submission, delaying approval to April 1, 2016.

Airxpanders chief executive officer Scott Dodson told a teleconference that after reviewing the 510k submission filed on September 1, 2015, the FDA decided that there were sufficient technical differences between the Aeroform carbon dioxide reservoir and patient-controlled expansion system and the existing saline systems to merit a de novo application.

"It is essentially a reformatting exercise," Mr Dodson said.

Mr Dodson said that there was no requirement for additional data and the same review team would review the new application which he hoped to file "in the next two weeks".

Mr Dodson said that the delay would have no material impact on the company which had \$23,394,000 in cash at September 30, 2015 with a three-month cash burn of \$4,019,000.

Mr Dodson told Biotech Daily after the teleconference that the company had budgeted for two 90-day 510k periods, because it was not always usual for the FDA to approve those applications on the first past.

Mr Dodson said that the 510k process was an iterative or collaborative and after filing the application the company could be told there were deficiencies with a new filing required.

He said that under the de novo system, the company and the regulator were in constant communication and any issues could be resolved quickly.

Mr Dodson said the delay was about one month from its original timeline.

In a media release Mr Dodson said the de novo process was used when there was no identical predicate device in the same medical field upon which to make comparisons.

"With the clearance of the Aeroform system through the de novo process as a low to moderate risk device, Aeroform would become its own predicate for future submissions," Mr Dodson said.

Airxpanders said that the 510(k) process allowed for a 90-day review period while the de novo process had a 120-day review cycle.

Airxpanders fell 7.5 cents or 8.3 percent to 82.5 cents.

MEDICAL AUSTRALIA

Medical Australia says the divestment of its US Medivet Biologics business reached an advance stage of negotiation but "has not to date produced any viable options".

In June, the company said it would focus on its human health business which had revenue and profit growth and divest its animal health business (BD: Jun 23, 2015).

Medical Australia said that in 2013 it acquired the animal health and stem cell technology provider Medivet Pty Ltd (BD: Jun 6, 10; Dec 10, 2013).

The company said it was "continuing to explore all options for disposal/divestment of the US business including any necessary provisioning ... in the half-year accounts".

Medical Australia said the human health business continued "to perform to plan".

Medical Australia was untraded at 6.6 cents.

NUSEP HOLDINGS

Nusep says it has an out-of-court settlement with former managing-director Prakash Patel in relation to his claim on termination of his employment.

Nusep said the settlement of \$200,000 would be paid in two instalments with the first instalment to be paid on December 14, 2015 and the second on January 13, 2016

Nusep was untraded at 4.1 cents.

LIVING CELL TECHNOLOGIES

Living Cell has a remuneration report first strike with the annual general meeting voting 25,591,800 votes (39.55%) against the report and 39,115,572 votes (60.45%) in favor. Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and at the later meeting, and if passed by more than 50 percent of votes, the directors must stand for re-election at a subsequent meeting within 90 days.

Living Cell said it had withdrawn resolutions to issue each of chairman Roy Austin and directors Prof Robert Elliott, Laurie Hunter, Dr Bernard Tuch and Robert Willcocks 300,000 options exercisable at 7.5 cents and 300,000 options exercisable at 10 cents, within three years of issue, as part of their directors remuneration (BD: Oct 13, 2015).

Founder and director Prof Elliott was re-elected overwhelmingly.

Living Cell's most recent Appendix 3B new issue announcement said it had 423,999,738 shares on issue, meaning that the votes against the remuneration report amounted to 6.0 percent of the company, sufficient to requisition extraordinary general meetings.

Last year the annual general meeting passed the remuneration report easily but there was substantial opposition to the ratification of the company's \$3 million placement at 6.08 cents a share, with 20,408,796 votes (31.4%) against and 44,641,605 votes (68.6%) in favor (BD: Oct 8, Nov 18, 2014).

Living Cell was up one cent or 22.2 percent to 5.5 cents.

BIOTA PHARMACEUTICALS

Biota says its annual general meeting has again voted strong dissent against the re-election of chairman Russell Plumb, as well as executive pay. (BD: Nov 13, 2014).

Last year, the Biota annual general meeting voted strong dissent against the then retiring chairman Dr Jim Fox and Mr Plumb who would become executive chairman and a non-binding vote on compensation for named executive officers faced 36.5 percent opposition. Today, Biota said that Mr Plumb faced 5,841,768 withheld votes (34.4%) but was supported by 16,800,353 votes (65.6%).

The company said that 2,696,034 votes (15.9%) were withheld from director Michael Dougherty with 14,266,681 votes (84.1%) in favor, while chief executive officer Dr Joseph Patti and directors Dr Geoffrey Cox, John Richard, Anne VanLent, Armando Anido and Dr Michael Dunne were re-elected overwhelmingly.

The non-binding compensation vote for named executive officers faced 4,432,111 "votes against" (32.8%) and 9,068,873 votes for (67.2%), with 7,479,042 broker non-votes.

Biota said it had a total of 38,609,086 shares on issue, meaning that the votes against Mr Plum amounted to 15.1 percent of the company.

Last year, Biota said that top-line data from its phase II 'Igloo' trial comparing 40mg and 80mg laninamivir octanoate to placebo showed no significant benefit and following the termination of its \$US231 million 2011 Biomedical Advanced Research and Development Authority (BARDA) contract, Biota said it would close its Australian operations and sack more staff (BD: Jun 3, Aug 4, 2014).

Biota was developing its long-acting neuraminidase inhibitor laninamivir octanoate, when it merged with Nabi Pharmaceuticals to access its \$US54 million in cash, eventually settling for \$US27 million (BD: Apr 1, 2011; Apr 23, Oct 30, 2012).

Last night on the Nasdaq, Biota was unchanged at \$US2.01 (\$A2.82, equivalent to 35.25 cents prior to the Nabi merger, when it was trading around \$A1.00), with 7,927 shares traded.

PRANA BIOTECHNOLOGY

All resolutions at the Prana annual general meeting were passed, but the remuneration report facing up to 17.8 percent opposition.

Prana said that the vote on the remuneration report saw an initial 8,274,152 votes (17.8%) in opposition with 38,159,479 votes in favor (82.2%), but when 2,559,018 undirected proxies were voted by the chairman support increased to 40,718,497 votes (83.11%) with 8,274,152 votes (16.89%) against.

The company said the re-election of director Dr George Mihaly and the approval of the 10 percent placement capacity were passed by wider margins with the ratification of previously issued shares and the employee share plan passed overwhelmingly.

Prana's most recent Appendix 3B said it had 533,891,470 shares on issue meaning that the votes against the remuneration report amounted to 1.55 percent of the company's shares on issue, not sufficient to requisition extraordinary general meetings.

Prana fell half a cent or 4.35 percent to 11 cents.

SIMAVITA

Simavita's annual general meeting will vote to increase the non-executive director fee pool by \$150,000 or 42.9 percent to \$500,000 and fix the board at six directors.

Simavita said the meeting would also vote on the remuneration report, the 10 percent placement capacity, increase the stock option plan from 14,745,548 shares to 18,449,047 shares and re-elect as directors chairman Michael Brown, chief executive officer Philippa Lewis, Ari Bergman, Warren Bingham, Damien Haakman and Craig Holland.

Simavita was up one cent or 2.7 percent to 38 cents.

BIONOMICS

Bionomics says it will co-host a one-day symposium with Merck & Co on drug discovery and development for cognition and Alzheimer's disease, next Monday.

Bionomics said it was the third annual symposium with the Kenilworth, New Jersey based Merck & Co, (Merck Sharp and Dohme (MSD) outside the US and Canada) and would be "the biggest to date" with more than 200 registrations from researchers, medical personnel and patient support groups as well as investors and life science analysts.

The company said that chief executive officer Dr Deborah Rathjen would open the Adelaide symposium and the closing address would be given by MSD Australia and New Zealand managing-director Dr Susanne Fiedler.

Bionomics said that the keynote presentation would be given by MSD head of neuroscience Dr Darryle Schoepp on 'Challenges in neuroscience discovery and development: what has changed and where are we headed'.

The company said that Bioxcel head of central nervous system research and development Dr Frank Yocca would will present on the topic 'Emerging area for drug development: psychiatric based symptoms of neurodegenerative disorders and Biogen head of discovery science Dr Richard Hargreaves would speak on the 'Use of imaging for neuroscience drug discovery and development.

Bionomics said the symposium would be at Crowne Plaza, Hindmarsh Square, Adelaide on November 16, 2015 and for free registration email lnicotra@bionomics.com.au.

Bionomics fell half a cent or one percent to 51 cents.