



Biotech Daily

Tuesday July 23, 2019

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: AMPLIA UP 24%; RESONANCE DOWN 7%**
- * **AMPLIA: 'AMP945 REDUCES TUMOR SIZES AND FAK IN MICE'**
- * **PHYLOGICA: 'PEPTIDES DELIVER 4 TIMES ANTISENSE DRUG IN MICE'**
- * **REGENEUS: 'PROGENZA REVERSES ALLODYNIA IN RATS'**
- * **ASX QUERIES BENITEC XMAS EVE BB-401 TRIAL NEWS**
- * **PALLA (TPI) \$36m UNNAMED EUROPEAN CODEINE DEAL**
- * **SOMNOMED RECEIPTS UP 8% TO \$65m**
- * **COGSTATE RECEIPTS DOWN 7% TO \$40m**
- * **EXPANDED ALCIDION RECEIPTS UP 416% TO \$21.5m**
- * **MACH7 RECEIPTS UP 8% TO \$10m**
- * **USCOM RECEIPTS UP 21.5% TO \$2.5m**
- * **THOMAS JEFFERSON JOINS GI DYNAMICS ENDOBARRIER TRIAL**
- * **PHARMAUST PLEADS SCHULTZ, DOG NEWS TO ASX 26% QUERY**
- * **TRIBECA TAKES 5% OF CANN**
- * **HYBRID HOLDINGS TAKES 7.5% OF PHARMAUST**
- * **NEW H2 TAKES 18% OF BOD, TRIBECA 8%, SG HISCOCK BELOW 5%**
- * **SIENNA TO RELEASE 27m ESCROW SHARES**
- * **MEDIBIO CAPITAL RAISING, 21.6m MANAGEMENT OPTIONS EGM**
- * **SIMAVITA APPOINTS ALAN FISHER DIRECTOR, MICHAEL SPOONER EXEC**
- * **NEW ELIXINOL JOBS FOR ETTENSON, SMITH, HARRISON, ATCHA**
- * **BOD APPOINTS AKASH BEDI, PATRICE MALARD H&H DIRECTORS**

MARKET REPORT

The Australian stock market was up 0.5 percent on Tuesday July 23, 2019, with the ASX200 up 33.4 points to 6,724.6 points.

Nineteen of the Biotech Daily Top 40 stocks were up, 10 fell, nine traded unchanged and two were untraded.

Amplia was the best, up three cents or 24 percent to 15.5 cents, with 1.4 million shares traded, followed by Compumedics up 10.1 percent to 81.5 cents with 570,751 shares traded and Dimerix up 10 percent to 11 cents with 28,393 shares traded.

Proteomics climbed 6.1 percent; Oncosil was up 5.8 percent; Opthea, Orthocell and Universal Biosensors improved more than four percent; Uscom was up 3.7 percent; Antisense, Ellex, Nanosonics, Polynovo and Prescient rose more than two percent; Cochlear, Cynata, Cyclopharm and Pro Medicus were up more than one percent; with Clinuvel, CSL and Starpharma up by less than one percent.

Resonance led the falls, down one cent or 6.9 percent to 13.5 cents, with 1.8 million shares traded.

Telix lost 5.5 percent; Patrys fell four percent; Alterity (Prana) was down 3.6 percent; Optiscan and Pharmaxis shed more than two percent; Avita, Benitec and Medical Developments were down more than one percent; with Mesoblast and Resmed down by less than one percent.

AMPLIA THERAPEUTICS (FORMERLY INNATE IMMUNOTHERAPEUTICS)

Amplia says its AMP945 for fibrotic diseases reduces squamous cell carcinoma tumors by about half and focal adhesion kinase to undetectable in mice.

Amplia said that “AMP945 exerts several effects that are consistent with the potential to restore the patient's own anti-tumor immune response”.

The company provided mouse data showing that, as a single agent, AMP945 reduced CD206+ macrophages, granulocytic myeloid-derived suppressor cells and endothelial cells at greater levels than controls.

Amplia said that tumor-associated CD206+ macrophages and granulocytic myeloid-derived suppressor cells were known to contribute to the suppression of anti-tumor immune responses, tumor growth and metastases, or development of secondary malignant tumors from the primary cancer.

The company said that the study, led by the University of Edinburgh's Dr Alan Serrels, showed that tumors in mice treated with AMP945 were “approximately half” of the size of tumors in mice treated with non-active vehicle after 15 days treatment.

Amplia said that levels of the phosphorylated form of focal adhesion kinase (FAK) were “undetectable” which suggested the complete inhibition of FAK in the mice treated with AMP945.

Amplia chief executive officer Dr John Lambert said “we consider the results of this study to be highly encouraging and the data further confirms Amplia's view that our lead drug candidate AMP945 should be advanced into clinical development as quickly as possible”.

The company said future studies would assess the effects of AMP945 when used in combination with other immune oncology products.

Amplia was up three cents or 24 percent to 15.5 cents with 1.4 million shares traded.

PHYLOGICA

Phylogica says that its cell penetrating peptide platform is able to deliver four times the amount of antisense drug to retina targets in mice than existing delivery platforms. Phylogica said that its second-generation cell penetrating peptides, formerly known as Phylomers, were more than 400 percent more effective than the gold standard peptides at achieving “exon skipping, the desired effect of a drug cargo” at day-7 post-administration. The company said that the magnitude of outperformance increased the longer the experiments continued and the peptides had “a significantly improved safety profile on systemic injection than the gold standard”.

Phylogica chief executive officer Dr Rohan Hockings told Biotech Daily that his company’s peptide delivery platform was able to deliver four times the amount of drug to the retina targets than other peptides.

The company said in a media release that the result was “significant given that the rate-limiting step for the development of delivery technologies is the amount of cargo that can be safely delivered inside a cell”.

Phylogica said the lead program was “directed towards delivering ... an antisense oligo-nucleotide into the retina of mice”.

The company said that the retina at the back of the eye could be affected by a variety of blinding diseases, with inherited retinal diseases its priority.

Phylogica said that at seven days post-administration, its cell penetrating peptide delivered 1.6 micrograms of survival of motor neuron 1 (SMN1) antisense oligo-nucleotide cargo into the retinal pigment epithelium and choroid layer of the eye achieving a 33 percent change in transcription compared to the existing RXR4 peptide’s eight percent.

The company said that a dose escalation study found that existing peptides showed signs of toxicity at 10mg/kg and 20mg/kg but the Phylogica peptides “demonstrated minimal toxicity at doses of 40mg/kg”.

Phylogica was up 0.2 cents or 7.4 percent to 2.9 cents with 3.6 million shares traded.

REGENEUS

Regeneus says one injection of its Progenza reverses the neuropathic pain of allodynia in rats 14 days following treatment.

Regeneus said allodynia was “a condition in which pain occurs from what is normally non-painful stimulation of the skin, such as light touch”.

The company said Progenza was an allogeneic, off-the-shelf, fat-based, stem cell technology platform developed for the treatment of musculoskeletal diseases with the potential to be used for other inflammatory diseases.

Regeneus said the trial, completed with the University of Adelaide’s Prof Mark Hutchinson, induced an injury to the sciatic nerve of the hind limb on the rats causing allodynia to develop.

The company said that a single dose of Progenza or a vehicle was administered by intrathecal injection 14 days following the injury.

The company said that 14 days following the injection that the allodynia in rats treated with Progenza was gradually reversed “to a level that is not significantly different than prior to injury”.

Prof Hutchinson said “it is uncommon to identify treatments that create long-lived reversal of exaggerated pain states lasting weeks after single doses”.

“In our model of exaggerated pain behaviors, Progenza was capable of this long-term complete reversal of the exaggerated pain behavior”.

Regeneus was unchanged at 10.5 cents.

BENITEC BIOPHARMA

Benitec has told the ASX that results from its trial of BB-401 for head and neck cancer were published “earlier than anticipated”.

At 6.10pm (AEST) on Friday December 21, 2018, after the market closed for the Christmas break, Benitec said that BB-401 for head and neck cancer did not meet the objective response rate to continue enrolment in the phase II study (BD: Jan 20, 2018). The company said at that time that BB-401 was “fundamentally different” from its other DNA-directed-RNA-interference drugs.

Today, Benitec responded to ASX questions on both the trial results and a planned “new proprietary pipeline program” to be unveiled by March 31, 2019.

The ASX said that the expected timeframes for the milestones had passed without an update.

Benitec told the ASX that the BB-401 trial results were published on December 21, 2018, earlier than anticipated, but did not note that this was after the market closed for the Christmas holidays.

The company said that the December announcement “stated that additional details would be disclosed following the completion of the comprehensive analyses of the clinical data derived from ongoing patient follow-up [but] this has not yet occurred, and the company is not currently in a position to provide further information on this”.

Benitec said that in regards to the proprietary programs update it had identified “select proprietary programs but these decisions are not yet final”.

“As soon as the company has finalized the decision and is in a position to make a definitive announcement in relation to the proprietary programs update, it will do so,”

Benitec said, expecting the announcement by October 2019.

Benitec fell 0.1 cents or 1.9 percent to 5.1 cents.

PALLA PHARMA (FORMERLY TASMANIAN POPPY INDUSTRY ENTERPRISES)

Palla Pharma says it has a US\$25,000,000 (\$A35,614,054) supply agreement with an unnamed European customer for 24 tonnes of codeine phosphate a year for three years.

Palla Pharma said it would supply the codeine in a granulated or tablet form.

Palla Pharma was up 15 cents or 13.1 percent to \$1.295.

SOMNOMED

Somnomed says that receipts from customers for the year to June 30, 2019 improved 7.7 percent to \$65,133,000 compared to previous corresponding period.

Somnomed said that receipts from customers for its mouthguard sleep apnoea devices the three months to June 30, 2019 were up 5.5 percent to \$17,947,000 compared to the previous year.

The company said it had cash and cash equivalents of \$13,383,000 at June 30, with an expected outflow of \$18,300,000 for the three months to September 30.

Somnomed said that its revenue was driven by North American direct dental sales, which grew by 31 percent.

Somnomed was up 24 cents or 16 percent to \$1.74.

COGSTATE

Cogstate says receipts from customers for the year to June 30, 2019 fell 6.7 percent to \$US28,087,353 (\$A40,013,909) compared to previous corresponding period.

Cogstate said that receipts from customers for the provision of cognitive testing services for the three months to June 30, were down 7.0 percent to \$US6,761,664 compared to the previous year.

The company said it had cash and cash equivalents of \$US3,216,019 at June 30, with an expected outflow of \$US8,453,793 for the three months to September 30.

Cogstate fell three cents or 13.6 percent to 19 cents.

ALCIDION

Alcidion says that receipts from customers for the year to June 30, 2019 were up 416.2 percent to \$21,501,000 compared to previous corresponding period.

Alcidion said that receipts from customers for its hospital information systems for the three months to June 30 fell 0.9 percent to \$6,124,000, compared to the previous year.

In 2018, Alcidion said it bought MKM Health and Patientrack, which were expected to make a "significant contribution" to revenue and profitability (BD: Apr 24, 2018).

Today, the company said it had cash and cash equivalents of \$3,371,000 at June 30, with an expected outflow of \$5,754,000 for the three months to September 30.

Alcidion fell 3.5 cents or 18.4 percent to 15.5 cents with 15.3 million shares traded.

MACH7 TECHNOLOGIES

Mach7 says that receipts from customers for the year to June 30, 2019 rose 8.3 percent to \$10,339,000 compared to the previous corresponding period.

Mach7 said receipts from customers for its imaging systems and services for the three months to June 30 fell 0.5 percent to \$2,331,000 compared to the previous year.

The company said it had a cash burn of \$407,000 for the three months to June 30, cash and cash equivalents of \$2,267,000 at June 30, a loan of \$622,000, and an expected outflow of \$2,721,000 for the three months to September 31, 2019.

Mach7 said that it expected "to be cash-flow break-even" for the 12-month period to February 2020.

Mach7 fell 2.5 cents or 3.1 percent to 77 cents.

USCOM

Uscom says that receipts from customers for the year to June 30, 2019 were up 21.5 percent to \$2,530,918 compared to previous corresponding period.

Uscom said that receipts from customers for all Uscom products, including the Uscom 1a ultra-sonic cardiac output monitor, the BP+ and the Spirosonic respiratory test, for the three months to June 30, 2019 rose 44.2 percent to \$760,136 compared to previous corresponding period.

The company said it had a cash burn of \$437,722 for the three months to June 30, cash and cash equivalents of \$1,208,496 at June 30, with an expected outflow of \$953,000 for the three months to September 31, 2019.

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

GI DYNAMICS

GI Dynamics says that Philadelphia's Thomas Jefferson University hospital will be the fourth site to join its pivotal US Endobarrier trial for obesity and type 2 diabetes.

Previously, GI Dynamics said that the trial sites included the Ann Arbor-based University of Michigan, the Houston, Texas Baylor College of Medicine and Boston's Brigham and Women's Hospital as the lead clinical site (BD: Jun 13, Jul 11, 2019).

Today, the company said the randomized Endobarrier and control arms would receive "identical lifestyle therapy", with the primary endpoint a reduction in average blood sugar levels at 12 months of treatment.

GI Dynamics was untraded at 3.4 cents.

PHARMAUST

Pharmaust has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said that Pharmaust's share price increased 1.4 cents or 25.9 percent from 5.4 cents on July 22 to 6.8 cents today and noted a "significant increase" in trading.

Pharmaust said the recent trading was "primarily due to the increased awareness in the market place of Pharmaust" and the progress of its monepantel program including ethics approval for its phase II dog trial (BD: Jul 15, 2019).

Pharmaust was up 1.4 cents or 25.9 percent to 6.8 cents with 3.4 million shares traded.

CANN GROUP

Sydney's Tribeca Investment Partners says it has become a substantial shareholder in Cann Group with 7,167,485 shares or 5.05 percent of the company.

The substantial shareholder notice said that between March 18 and July 18, 2019 Tribeca bought and sold shares with the single largest purchase 215,450 shares for \$445,551 or \$2.07 a share.

Cann Group was up eight cents or 3.8 percent to \$2.20.

PHARMAUST

Perth's Hybrid Holdings says it has increased in Pharmaust from 10,273,851 shares or 5.16 percent to 21,000,000 shares or 7.49 percent.

The substantial shareholder notice Hybrid director Graham Darcy said the company acquired 10,726,149 shares between June 28, 2018 and July 17, 2019 at prices ranging from 2.5 cents a share to 5.3 cents a share.

BOD AUSTRALIA

Health & Happiness and New H2 say they have acquired 14,864,865 shares or 17.64 percent of the company.

The substantial shareholder notice said the Hong Kong-based groups acquired all shares on July 22, 2019 for \$5,500,000 or 37 cents a share.

Last week, Bod said Health & Happiness would pay \$1.5 million, invest \$5.5 million to commercialize marijuana products and take two board seats (BD: Jul 19, 2019).

Bod was unchanged at 47 cents.

BOD AUSTRALIA

Tribeca Investment Partners says it increased its substantial shareholding in Bod from 4,345,332 shares (6.26%) to 5,595,332 (8.06%).

The Sydney-based Tribeca Investment said it bought 1,250,000 shares on July 19, 2019 for \$462,500 or 37 cents a share.

Sydney's SG Hiscock and Co says it has ceased its substantial shareholding in Bod, through the issues of shares.

SIENNA CANCER DIAGNOSTICS

Sienna says that 24,426,629 shares will be released from a 24-month ASX escrow on August 3, 2019.

Biotech Daily calculates that following the release of shares from escrow, the company will have 289,055,171 shares available for trading.

Sienna was up 0.6 cents or 10 percent to 6.6 cents.

MEDIBIO

Medibio will hold an extraordinary general meeting to approve a \$4,020,000 capital raising and the issue of 21.6 million management options.

Medibio said shareholders would vote to ratify the issue of shares and options relating to the placement earlier this month (BD: Jul 10, 2019).

The company Medibio said it proposed to grant 15,000,000 options to chief executive officer David Kaysen as a performance incentive, 2,600,000 options to director Melanie Leydin in consideration for her services and 4,000,000 options to executive Jennifer Solitario, the wife of director Claude Solitario, as part of her remuneration all exercisable at the price of shares on the date of grant and within five years.

The meeting will be held at Gadens Lawyers, Level 25, 600 Bourke Street, Melbourne, on August 19, 2019 at 11am (AEST).

Medibio was up 0.1 cents or 5.9 percent to 1.8 cents with 17.4 million shares traded.

SIMAVITA

Simavita says it has appointed Alan Fisher as a director with chairman Michael Spooner appointed executive chairman.

Simavita said Mr Fisher was chairman of Centerpoint Alliance and IDT Australia, and a director of Thorney Technologies and Bionomics.

Simavita was unchanged at two cents.

ELIXINOL GLOBAL

Elixinol says it has appointed executives Gabriel Ettenson, Greg Smith, Leif Harrison and Ali Atcha to new roles executives.

Elixinol said US branch president Mr Ettenson would be chief technology officer, US information technology director Mr Smith chief information officer, US business development director Mr Harrison would become Elixinol Americas chief executive officer and Europe sales and marketing head Mr Atcha would be Europe and UK chief executive. Elixinol chief executive officer Stratos Karousos said the changes "recognize the skills, capabilities and track record of key executives".

Elixinol fell three cents or 0.8 percent to \$3.90 with 267,742 shares traded.

BOD AUSTRALIA

Bod says it had appointed Akashi Beda and Patrice Malard as non-executive directors, following the investment to develop marijuana products (BD: Jul 19, 2019).

Bod said Mr Beda was H&H Group strategy and corporate affairs director and Mr Malard was chief technology officer and general manager of the technical centre.