



# Biotech Daily

Tuesday August 6, 2019

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH DOWN: IMMUTEP UP 5%; USCOM DOWN 18%**
- \* **IMMUTEP RIGHTS OFFER RAISES \$6m, TOTAL \$10m**
- \* **BOD DIRECTOR, MANAGEMENT OPTIONS RAISE \$1.2m**
- \* **SUDA: 'ZOLPIMIST SPRAY BEATS TABLETS FOR INSOMNIA'**
- \* **PAINCHEK: SINGAPORE APPROVAL; ALLIUM AGED CARE LICENCE**
- \* **PHYLOGICA: 'PEPTIDE EFFECTIVE IN RETINA TISSUE IN-VITRO'**
- \* **IMAGION FILES US FDA PRE-SUBMISSION**
- \* **CELLMID: INDIA'S K2B SOUTH KOREA ÉVOLIS DISTRIBUTOR**
- \* **CRESO APPOINTS MEDLEAF NZ MARIJUANA DISTRIBUTOR**
- \* **VOLPARA AGM: 900k DIRECTOR OPTIONS**
- \* **BOD CEO JOANNE PATTERSON INCREASES, DILUTED TO 7.8%**
- \* **NAOS TAKES 19.65% OF BTC**
- \* **BTC APPOINTS PETER MEARS ADVISOR**

## MARKET REPORT

The Australian stock market lost 2.44 percent on Tuesday August 6, 2019, with the ASX200 down 162.2 points to 6,478.1 points. Five of the Biotech Daily Top 40 stocks were up, 26 fell, seven traded unchanged and two were untraded. All three Big Caps fell.

Immutep was the best, up 0.1 cents or 4.8 percent to 2.2 cents with 2.5 million shares traded. Impedimed 4.2 percent; Osprey and Resonance were up three percent or more; with Compumedics up 1.6 percent.

Uscom led the falls, down 2.5 cents or 17.9 percent to 11.5 cents, with 279,152 shares traded. Pro Medicus lost 14.9 percent; Polynovo fell 9.2 percent; Oncosil was down 8.45 percent; Antisense, Prescient and Telix shed more than six percent; Clinuvel, Genetic Signatures, Kazia, LBT and Proteomics fell five percent or more; CSL, Dimerix, Medical Developments, Mesoblast, Patrys and Volpara fell four percent or more; Amplia, Cochlear and Paradigm were down more than three percent; Cyclopharm, Neuren, Next Science, Pharmaxis, Resmed and Starpharma shed two percent or more; with Ellex and Nanosonics down more than one percent.

## IMMUTEP

Immutep says its one-for-11.8 entitlement offer at 2.1 cents a share has raised \$6,000,000, bringing the total raised to \$10,000,000.

In July, Immutep said \$4 million was raised through a placement to new and existing shareholders including Australian Ethical Investment, Platinum Investment Management and Altium Capital Management (BD: Jul 9, 2019).

Today, the company said the offer had applications for \$2,721,190 in shares, with a shortfall of \$3,309,366 of shares, which was fully-underwritten by Bell Potter Securities. Immutep said the funds would be used to develop of its programs and to pursue regulatory pathways for its lead product IMP321, or efitlagimod alpha.

Immutep was up 0.1 cents or 4.8 percent to 2.2 cents with 2.5 million shares traded.

## BOD AUSTRALIA

Bod says it has raised \$1,200,000 through the exercise of 4,500,000 options held by directors and management for an average of 26.7 cents a share.

Bod said options holders sold 1.9 million shares to investors and an Australian institution to exercise the options.

In its Appendix 3B, the company said 1,500,000 options were exercised at 20 cents each, with three groups of 1,000,000 options exercisable at 25, 30 and 35 cents each.

Bod said that it had \$11,000,000 in cash and cash equivalents.

Bod fell five cents or 8.85 percent to 51.5 cents.

## SUDA PHARMACEUTICALS

Suda says a 43-patient phase III study shows that Zolpimist lingual spray for insomnia delivers sleep onset more quickly than the zolpidem tablet.

Suda said the four-arm, crossover study came from a post-hoc analysis of the pivotal phase III trial of Zolpimist by US marketing authorization holder Aytu Bioscience and compared five and 10 milligram doses of Zolpimist to zolpidem tablets, branded as Ambien, in 20 male and 23 female patients seeking short-term treatment for insomnia. The company said the blood serum therapeutic threshold for zolpidem in treatment of insomnia was a blood plasma concentration of 20 nanograms per milliliter.

Suda said Zolpimist outperformed Ambien for both doses, achieving the threshold at seven minutes, compared to Ambien's 15 minutes, for the 10mg dose, and 10.5 minutes, compared to Ambien's 17.2 minutes, for the 5mg milligram dose.

The company did not statistical significance values.

Suda said Zolpimist outperformed Ambion on the digit symbol substitution test, which assessed attention, perceptual speed, motor speed, visual scanning and memory.

The company said Zolpimist achieved an average time for a five-point change from baseline in the test at 4.8 minutes and 8.0 minutes, for the 10mg and 5mg doses, respectively, compared to Ambien's averages of 14.0 minutes and 16.2 minutes.

Aytu chief executive officer Josh Disbrow said the analysis showed "a more rapid onset of sleep and increased bioavailability of Zolpimist when compared to zolpidem tablets".

"The novel oral spray form embodied in Zolpimist may present patients with a more convenient form and a simple way to achieve rapid sleep onset," Mr Disbrow said.

"For the first time this study has established the clinical proof demonstrating fast sleep onset and the distinct pharmacokinetics of Zolpimist that support its use in the short-term treatment of insomnia."

Suda was up 0.05 cents or 12.5 percent to 0.45 cents with 9.4 million shares traded.

## PAINCHEK

Painchek says Singapore has approved its products, and it has a two-year licence agreement with Singapore nursing home operator Allium Healthcare.

Painchek said Allium would provide its smart phone-based pain assessment and monitoring application to its 129-bed nursing home, day-care facilities and home care services.

The company said that Allium would use its Painchek software across all facilities at prices ranging between \$5 and \$10 per patient per month.

Painchek said that a Singapore study found that one in 10 people over the age of 60 years “may have dementia”.

The company said that the study estimated that about 82,000 currently had dementia with more than 100,000 people expected to be affected by dementia “in a few years’ time”.

Allium chief executive officer Bernie Poh said the company would investigate “evidence-based technology” to help provide personalized and dignified care to its patients.

“The Painchek [application] provides us with the capability to better assess and quantify our clients’ pain levels so that we can enhance their treatment plans,” Mr Poh said.

Painchek managing director Phillip Daffas said the regulatory approval and licencing agreement could “be a platform for the broader Asian markets, where there is a large ageing population”.

“Many people in Asia living with dementia have a desire to remain living at home and often have good family support,” Mr Daffas said.

“The Painchek shared care program will provide the capability for Allium to provide accurate pain assessments across the continuum of care and help those people live life the way they want,” Mr Daffas said.

Painchek was up half a cent or 2.9 percent to 17.5 cents with 6.9 million shares traded.

## PHYLOGICA

Phylogica says its cell penetrating peptide technology can deliver an anti-sense oligonucleotide into human retinal pigment epithelial cells, in-vitro.

Last month, Phylogica said that its second-generation cell penetrating peptides, formerly known as Phylomers, were able to deliver four times the amount of antisense drug to retina targets in mice than existing delivery platforms (BD: Jul 23, 2019).

The company said at that time that its peptides 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

Today, Phylogica said that with its peptide technology the anti-sense oligonucleotide achieved 100 percent exon-skipping in human cells, compared to the eight percent exon-skipping achieved without the technology.

The company said the results demonstrated the efficacy of the peptide in delivering the anti-sense oligonucleotide inside the cell to enable it to engage with its target, messenger ribonucleic acid or mRNA.

Phylogica said it planned to finalize the pre-clinical studies of the peptides by testing the technology in three dimensional retinal organoids by the end of 2019.

The company said it intended initiating investigational new drug enabling studies for clinical evaluation next year.

Phylogica was up 0.1 cents or 2.9 percent to 3.6 cents with 52.2 million shares traded.

## IMAGION BIOSYSTEMS

Imagion says it has filed a pre-submission application to the US Food and Drug Administration for the first in-human study of its Magsense for breast cancer detection. Imagion said that following FDA guidance it filed the pre-submission ahead of filing for an investigational device exemption, a US regulatory requirement for human studies with medical device.

Imagion executive chairman Bob Proulx said the recent breakthrough device designation for its non-radioactive imaging technology, Magsense, allowed an expedited review of the submission.

“While the designation does not change the compliance requirements, we expect it will improve the speed with which we receive feedback from the agency and reduce the risk of disruptions to our plans for undertaking a first-in-human study,” Mr Proulx said.

Imagion said that following a review of the pre-submission, the company would be able to schedule a meeting to discuss questions related to the investigational device exemption.

Imagion was up 0.4 cents or 9.3 percent to 4.7 cents with 1.8 million shares traded.

## CELLMID

Cellmid says it has a five-year distribution agreement with K2B Co for its Évolis hair care products in South Korea.

Cellmid said the agreement with the Chennai, Tamil Nadu, India-based K2B Co, was through subsidiary Advangen International, with an expected launch by July 1, 2020, following registration with the South Korean Ministry of Food and Drug Safety.

The company said that undisclosed minimum order requirements would begin in the first year with an expected increase over the subsequent two years.

Cellmid was up half a cent or 2.3 percent to 22 cents.

## CRESO PHARMA

Creso says it has appointed Auckland’s Medleaf Therapeutics to distribute its Cannaqix50 for chronic pain and its cannabidiol oil in New Zealand.

In January, Creso said it would partner with Medleaf to build a comprehensive medical marijuana business which would distribute products in New Zealand (BD: Jan 9, 2019).

Today, the company said the agreement included undisclosed purchase targets.

Creso fell one cent or 2.4 percent to 41 cents.

## VOLPARA HEALTH TECHNOLOGIES

Volpara shareholders will vote to grant directors John Diddams and John Pavlidis 900,000 options at current prices.

Volpara said it proposed to issue Mr Diddams and Mr Pavilidis 450,000 options each, vesting in four tranches and exercisable by August 20, 2026 at the higher of \$1.50 and the 30-day volume weighted average price to the day prior to the annual general meeting.

The notice of meeting said that shareholders would also vote on the re-election of directors Michael Brandy and Mr Pavlidis, the ratification of a previous issue of 12,019,985 shares, the renewal of the company’s employee share option plan, and the fixing of the auditor’s remuneration.

The meeting will be held at Area Events, The Zone Room, 1 O’Reily Avenue, Wellington, New Zealand on August 20, 2019 at 12pm (NZST).

Volpara fell 7.5 cents or 4.95 percent to \$1.44 cents with 1.4 million shares traded.

## BOD AUSTRALIA

Bod chief executive officer Joanna Patterson says she has increased and been diluted from 5,700,000 shares (12.38%) to 6,550,000 shares (7.77%).

Ms Patterson said that on January 17, 2019 she bought 100,000 shares for \$50,000 or 50 cents a share, on August 1 she exercised 1,500,000 options for \$450,000 or 30 cents each and on August 2 sold 750,000 shares for \$450,000 or 60 cents a share.

## BTC HEALTH

Naos Substantial Holders has increased in BTC from 30,064,724 shares (18.54%) to 48,165,801 shares (19.95%).

In a substantial shareholder notice, Naos said that on August 5, 2019 it bought 18,101,077 shares in the recent placement and on-market for \$1,489,681 or 8.23 cents a share.

In June, a BTC share plan raised \$1.2 million taking the total raised with a placement to \$9.2 million (BD: Jun 12, 2019).

BTC fell 0.1 cents or one percent to 9.9 cents.

## BTC HEALTH

BTC said it has appointed Peter Mears as an advisor “for new business opportunities and growth strategies for medical devices in ... Australia and New Zealand”.

BTC said Mr Mears had 30 years’ experience in the healthcare and medical device sectors and was the founder and managing director of Device Technologies New Zealand.