

Biotech Daily

Monday June 29, 2020

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: ANTISENSE UP 17%; NEUREN DOWN 13%
- * NEUREN RAISES \$20m, SHARE PLAN FOR \$3m MORE
- * IMMUTEP DOSES TACTI-002 STUDY PART A
- * AVITA US MOVE COMPLETES JULY 1
- * RESAPP US DEFENCE HEALTH ANALYTICS PROGRAM CLOSES
- * STARPHARMA: DEP-IRINOTECAN ANTI-TUMOR ACTIVITY, IN MICE
- * AMPLIA REQUESTS 'TOX STUDIES' TRADING HALT
- * MEDLAB: UK ORDERS 5k MG OPTIMA RELAX MARIJUANA UNITS
- * RESAPP LAUNCHES SLEEPCHECK APNOEA RISK APPLICATION
- * CRESO: 15m SHARES TO MERNOVA FOR SALES LICENCE MILESTONE
- * THORNEY, TIGA INCREASES, DILUTED TO 13.9% OF OVENTUS
- * L1 CAPITAL TAKES 7.4% OF CRESO
- * LITTLE GREEN PHARMA SHIPS MARIJUANA OIL TO UK
- * DR DAVID BROOKES REPLACES TALI DIRECTOR MARK SIMARI
- * SUDA CEO DR MICHAEL BAKER APPOINTED DIRECTOR

MARKET REPORT

The Australian stock market fell 1.51 percent on Monday June 29, 2020, with the ASX200 down 89.1 points to 5,815.0 points. Thirteen of the Biotech Daily Top 40 stocks were up, 22 fell, four traded unchanged and one was untraded. All three Big Caps fell.

Antisense was the best, up 1.1 cents or 16.9 percent to 7.6 cents, with 3.6 million shares traded. Actinogen climbed 9.1 percent; Alterity, Genetic Signatures and Proteomics improved six percent or more; LBT and Optiscan were up five percent or more; Avita was up 4.6 percent; Cyclopharm was up 3.05 percent; with Compumedics, Kazia, Polynovo and Volpara up one percent or more.

Neuren led the falls, down 22 cents or 13.4 percent to \$1.42, with 402,293 shares traded. Osprey lost 9.1 percent; Impedimed, Medical Developments and Paradigm retreated seven percent or more; Mesoblast, Next Science, Orthocell and Resonance were down six percent or more; Prescient lost 5.4 percent; Clinuvel and Oncosil fell four percent or more; Immutep, Imugene, Opthea and Telix were down more than three percent; Pharmaxis, Pro Medicus and Starpharma shed more than two percent; CSL and Dimerix were down more than one percent; with Cochlear, Cynata, Nanosonics and Resmed down by less than one percent.

NEUREN PHARMACEUTICALS

Neuren says it has raised \$20 million through a placement at \$1.40 a share and hopes to raise a further \$3 million through a share purchase plan at the same price.

Neuren said the issue price was at a 10 percent discount to the 10-day volume weighted average price of \$1.56 and a 15 percent discount to the last closing price of \$1.64.

The company said the share plan record date was June 26, the offer would open on July 9 and close on July 31, 2020, and the funds would be used for phase II trials of NNZ-2591 in three neurodevelopmental disorders and to pursue commercialization of trofinetide.

The company said MST Financial was lead manager and bookrunner for the placement. Neuren fell 22 cents or 13.4 percent to \$1.42.

IMMUTEP

Immutep says it has safely dosed the 36 patients in part A of its 109-patient, phase II, Tacti-002 study of IMP321 with Keytruda for cancers.

Immutep said the two stage, non-comparative, open-label, single-arm, multi-centre study would be conducted in collaboration with the Kenilworth, New Jersey-based Merck & Co at 12 sites across Australia, Europe, the UK and the US.

The company said part A would assess primary diagnosis-naïve first line non-small cell lung cancer (NSCLC), part B would assess primary diagnosis-refractory second line NSCLC and part C would assess primary diagnosis-naïve second line head and neck squamous cell carcinoma.

Immutep said 81 of 109 patients had been enrolled in the trial, with recruitment continuing for part B and stage two of part C and it expected to report more mature data by December 31, 2020.

Immutep fell half a cent or 3.2 percent to 15 cents with 1.5 million shares traded.

AVITA THERAPEUTICS

Avita says it has implemented its scheme of arrangement to redomicile to the US and its shares have been transferred to the Delaware-based Avita US.

Earlier this month, Avita said shareholders overwhelmingly supported the redomicile to the US, which was approved by the Federal Court of Australia (BD: Jun 15, 22, 2020). Today, the company said its Avita US Chess depositary interests would be dispatched to shareholders in Australia and would begin trading on a normal settlement basis on the ASX on June 30, 2020, with US shares to begin trading on the Nasdaq on July 1, 2020 under the Nasdaq code RCEL.

Avita was up 36 cents or 4.6 percent to \$8.17 with 1.7 million shares traded.

RESAPP HEALTH

Resapp says the US Defence Warfighter Analytics using Smartphones for Health program, which it has been working on since August 2018, has been closed. Resapp said that it provided the US Defence Advanced Research Projects Agency (Darpa) with audio-based algorithms to measure respiratory health.

Resapp chief executive officer Tony Keating said the company "made significant advances in audio-based algorithms for measuring health during the project".

"We continue to develop these audio-based algorithms as they offer a unique opportunity for passively monitoring a person's health".

Resapp fell one cent or 5.4 percent to 17.5 cents with 2.7 million shares traded.

STARPHARMA HOLDINGS

Starpharma says studies of dendrimer enhanced product-irinotecan and an anti-PD-1 antibody for colorectal cancer shows superior anti-tumor activity in two mouse models. Starpharma its dendrimer enhanced product (DEP) irinotecan was administered with either an anti-programmed cell death-1 (PD-1) antibody immune-oncology agent, or a vehicle control with the immune-oncology agent subcutaneously in three mouse studies. Starpharma said the studies aimed to measure improvement in survival and efficacy, with tumors measured twice weekly, and to compare DEP-irinotecan with conventional irinotecan.

The company said the CT-26 model of a highly aggressive colorectal cancer showed minimal impact when administered the anti-PD-1 antibody alone, but was greatly enhanced when combined with DEP-irinotecan.

Starpharma said the DEP-irinotecan and anti-PD-1 antibody combination in CT-26 mouse cancer cells had a statistically significantly greater anti-tumor effect measured by tumor size than antibody alone (p = 0.0002) and DEP irinotecan alone (p = 0.0146).

The company said the anti-tumor effect was statistically significantly greater compared to the antibody alone (p = 0.0001) in MC-38 mouse colorectal cancer cells.

Starpharma said survival was enhanced in both the CT-26 model (p = 0.0014) and the MC-38 model (p < 0.0001) when treated with DEP-irinotecan and the anti-PD1 antibody. The company said that median survival when administered DEP-irinotecan and anti-PD-1 antibody combination was 40 days compared to 13 days for the antibody alone in the CT-26 model and was 64 days compared to 22 days in the MC-38 model.

Starpharma said that the combination group had a significantly greater anti-cancer effect than the antibody alone (p = 0.0016) or with the conventional irinotecan combination with antibody (p = 0.0156).

The company said survival improved in the combination group (p < 0.0001), with median survival improving from 14 days with the antibody alone to 27 days in the CT-26 model, in a comparison of DEP irinotecan and conventional irinotecan with the anti-PD-1 antibody. Starpharma chief executive officer Dr Jackie Fairley said the company was "delighted to see the dual benefits of combining DEP-irinotecan with an immuno-oncology agent".

"These results indicate that DEP-irinotecan in combination with an anti PD-1 antibody could boost the efficacy over anti PD-1 antibody alone, or [immuno-oncology] combinations with standard chemotherapeutic agents," Dr Fairley said.

Dr Fairley said that immuno-oncology agents including anti PD-1 antibodies had "yielded excellent efficacy results in some patient groups" but up to 60 percent of patients did not respond to immuno-oncology treatments alone.

"In addition, there have been no observations of immune-mediated toxicities in patients treated with DEP- irinotecan," Dr Fairley said.

"Given immune-mediated toxicities can be problematic with [immuno-oncology] agents, the lack of overlapping side-effects further strengthens the rationale for combining [immuno-oncology] agents with DEP- irinotecan," Dr Fairley said.

Starpharma fell 2.5 cents or 2.15 percent to \$1.14 with 926,403 shares traded.

AMPLIA THERAPEUTICS

Amplia has requested a trading halt pending "an announcement to the market in relation to pre-clinical toxicology studies".

Trading will resume on July 1, 2020 or on an earlier announcement. Amplia last traded at 12 cents.

MEDLAB CLINICAL

Medlab says UK partner Cultech has placed its first order for 5,000 units of its hybrid magnesium and cannabidiol product Mg Optima Relax.

In December, Medlab said Cultech would distribute its Ordbiotic probiotic rehydration formulation and marijuana derivative, Nanocbd in the UK (BD: Dec 12, 2019).

Today, Medlab chief executive officer Dr Sean Hall said the product was "not for Australia because of our laws relating to [cannabidiol] use, but [is] primed for other global legal markets".

"We would envisage a more global play regarding this product, as most Westerners are well versed in the benefits of magnesium and hence it's relatively easy to understand the synergistic benefits of combining magnesium and [cannabidiol]," Dr Hall said. Medlab was up one cent or 7.1 percent to 15 cents.

RESAPP HEALTH

Resapp says it has launched its Sleepcheck at-home sleep apnoea screening application at the Apple App Store in Australia and the UK.

Resapp said the application analyzed breathing and snoring sounds to assess the risk of sleep apnoea.

The company said it would be available for \$7.99 and would be available for Android devices later this year.

CRESO PHARMA

Creso says it will issue 15,010,185 shares to Mernova vendors at 5.0 cents a share to settle part of a debt related to its second Mernova Medical acquisition milestone. In 2017, Creso said it would pay Mernova vendors \$C800,000 (\$A898,431) for the first milestone of obtaining a Canada cultivation licence and a second milestone of the same amount for obtaining a Canada sales licence (BD: Jul 27, 2017).

Creso fell 0.3 cents or 8.3 percent to 3.3 cents with 4.6 million shares traded.

OVENTUS MEDICAL

Thorney Technologies and Tiga Trading say they have increased and been diluted in Oventus from 13,929,019 shares (15.49%) to 22,013,646 shares (13.91%).

The Melbourne-based Thorney and Tiga said that between December 21, 2017 and June 18, 2020 they acquired the shares and were diluted in a series of on-market purchases placements, rights issues and share purchase plans, at prices ranging from 24 cents to 85 cents.

Last month, Oventus said it had raised \$6.65 million through a placement at 24 cents a share and earlier this month, said it had share plan subscriptions for \$12.64 million, which would be scaled back to \$2 million (BD: May 1, Jun 18, 2020). Oventus fell two cents or 6.6 percent to 28.5 cents.

CRESO PHARMA

The Cayman Islands-based L1 Capital Global Opportunities says it has become a substantial shareholder in Creso with 25,148,554 shares or 7.35 percent of the company.

LITTLE GREEN PHARMA

Little Green Pharma says it has shipped more than 1,000 units of its marijuana oil to Lyphe Group, the parent company of Astral Health.

In April, Little Green Pharma said it had exported "the first" Australian marijuana oil to the UK, distributed by UK specialist importer Astral Health through a purchase agreement (BD: Apr 15, 2020).

Today, the company said it did not expect potential sales revenue from the shipment to be financially material.

Little Green was up one cent or 2.8 percent to 36.5 cents.

TALI DIGITAL

Tali says Dr David Brookes will replace Mark Simari as a non-executive director, effective from today.

Tali said Dr Brookes had held board positions for ASX listed biotechnology companies, including as chairman of Reproductive Health Sciences or RHS.

The company said he was currently a non-executive director of Factor Therapeutics and Anatara Lifesciences and non-executive chairman of the Better Medical Group.

Tali said Dr Brookes held a Bachelor of Medicine and Bachelor of Surgery from the University of Adelaide and was a fellow of the Australian College of Rural and Remote Medicine.

Tali was unchanged at 2.4 cents with 3.3 million shares traded.

SUDA PHARMACEUTICALS

Suda says chief executive officer Dr Michael Baker has been appointed as a director, effective from July 1, 2020.

Last November, Suda said it had appointed Dr Baker as chief executive officer, effective from January 2, 2020, on a base salary of \$250,000 (BD: Nov 27, 2020).

Today, the company said Dr Baker's remuneration would remain unchanged. Suda was unchanged at 4.2 cents.