

Biotech Daily

Monday July 8, 2019

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: MESOBLAST UP 7%; BENITEC DOWN 5%
- * VOLPARA ADDS SCREENPOINT TRANSPARA FOR BREAST SCREENING
- * IMUGENE: 'HER-VAXX 80% TUMOR REDUCTION'
- * ELLEX: 4-YEAR LEAD TRIAL DATA SHOWS '2RT SLOWS AMD'
- * COGSTATE RAISES \$4m FROM AUSTRALIAN ETHICAL
- * CELLMID TELLS ASX 29% QUERY: 'NO CONFIDENTIALITY BREACH'
- * SOMNOMED: 500,000 PATIENTS TREATED WITH SOMNODENT
- * ANTEO, UNNAMED BRAND WORK ON BATTERY DENSITY
- * UBS TAKES 5% OF ADALTA
- * CRYSTAL AMBER TAKES 65% OF GI DYNAMICS
- * EMVISION RELEASES 300k ESCROW OPTIONS

MARKET REPORT

The Australian stock market fell 1.17 percent on Monday July 8, 2019, with the ASX200 down 79.1 points to 6,672.2 points. Thirteen of the Biotech Daily Top 40 stocks were up, 18 fell, eight traded unchanged and one was untraded. All three Big Caps fell.

Mesoblast was the best, up 10.5 cents or 7.3 percent to \$1.55, with 1.8 million shares traded. Antisense and Imugene climbed more than six percent; Ellex, Kazia and Opthea improved four percent or more; Medical Developments and Polynovo were up more than three percent; Clinuvel, Compumedics, Universal Biosensors and Volpara rose more than two percent; with Orthocell up one percent.

Benitec led the falls, down 0.3 cents or 5.1 percent to 5.6 cents, with 385,533 shares traded.

Actinogen, Cynata, Genetic Signatures, Patrys, Pharmaxis and Prescient fell more than four percent; LBT and Osprey were down three percent or more; Amplia, Cochlear and Paradigm shed two percent or more; Avita, CSL, Cyclopharm, Nanosonics, Optiscan Proteomics and Telix were down one percent or more; with Pro Medicus and Resmed down by less than one percent.

VOLPARA HEALTH TECHNOLOGIES

Volpara says it has an agreement to distribute Screenpoint Medical's Transpara software for breast cancer detection in Australia, New Zealand, the US and Asia.

Volpara chief financial officer Craig Hadfield told Biotech Daily that the combination of the previous MRS acquisition, along with the Nijmegen, Netherlands-based Screenpoint deal could increase the company's average revenue per user four-fold from \$US2.20 (\$A3.15) per patient to a potential \$US10 (\$A14.32) per patient (BD: Jun 3, 14, 2019).

The company said Transpara was "designed to help radiologists read screening mammograms by marking specific areas of the breast image as likely being cancer or not" and the agreement with Screenpoint was a five-year non-exclusive contract with automatic renewable rights and all revenue would be shared.

Volpara said that combining its systems with Transpara could "optimize the early detection of breast cancer, thereby reducing radiologist liability and risk and cut screening costs by potentially eliminating a reader in systems that deploy double-reading mammography". Volpara chief executive officer Dr Ralph Highnam said the agreement would help "expand the software toolkit" of Volpara, and would be "successful commercially, especially when it achieves its US clearance from the Food and Drug Administration for 3D breast images". The company said Screenpoint Medical held FDA 510(K) clearance for its 2D breast imaging and was in the process of applying for 3D clearance.

Volpara said that Screeenpoint was founded by Prof Mike Brady and Prof Nico Karssemeijer, who were also co-founders of Volpara.

Volpara was up 4.5 cents or 2.8 percent to \$1.67 with 976,028 shares traded.

IMUGENE

Imugene says that one of three patients in cohort 3 of its phase Ib HER-vaxx gastric cancer vaccine study has had an 80 percent tumor reduction at day 266.

Last year, Imugene said HER-Vaxx was safe at 10, 30, and 50 micrograms (µgm) and antibody responses increased at all doses (BD: Dec 17, 2018).

In April, the company said the trial had one complete response and five partial responses and that all those treated at the highest dose of 50µgm had a partial response with two demonstrating a greater than 40 percent reduction in tumor size, along with higher antibody levels (BD: Apr 2, 2019).

In June, Imugene said that tumors in all patients either "shrunk further or stabilized" with one patient's tumor reduced by 70 percent, and patients continued to receive HER-Vaxx every three months to maintain cancer-targeting antibodies (BD: Jun 4, 2019).

Today, the company said that results from the three-patient cohort, presented at the European Society for Medical Oncology World Congress on Gastrointestinal Cancer in Barcelona over the weekend, showed that patients had maintained strong levels of antibodies targeting human epidermal growth factor receptor 2 (HER-2) which suggested that no resistance was developing.

Imugene said cohort three received the "optimal biological dose" with one patient showing a tumor reduction of 80 percent, with one of four lesions immeasurable at day-266. The company said that a phase II HER-Vaxx trial began in March 2019 and would be completed in 2020.

Imugene chief executive officer Leslie Chong said the latest presentation "further reinforces the very good early results and ongoing interest among the international oncology community in our potentially promising B-cell platform cancer vaccine and clinical development strategy".

Imugene was up 0.1 cents or 6.7 percent to 1.6 cents with 5.3 million shares traded.

ELLEX MEDICAL LASERS

Ellex says a four-year follow-up of 183 patients shows its retinal rejuvenation treatment (2RT) has a "rejuvenating" impact on the retina and potential for early intervention. Last year, Ellex said its three-year 292-patient, randomized, multi-centre, 'laser intervention in age-related macular degeneration' (Lead) trial missed its primary endpoint, but showed a reduction in the progression to late stage age-related macular degeneration (AMD) in 76 percent of 2RT patients, with 13.6 percent of the 2RT group and 17.2 percent of the control group developing late AMD (p = 0.122) (BD: Sep 21, 2018).

Today, the company said 183 of the initial 292 patients, or 63 percent, attended a fourth year post 'Lead' follow up visit and at 48 months, patients without coexistent reticular pseudo-drusen (RPD) showed a clinically and statistically significant 72 percent reduction in the rate of progression to late AMD compared to the control group (p = 0.002) Ellex chief executive officer Ged Wallace said the follow up data showed the "restorative effects of 2RT on retinal health in selected patients with [intermediate] AMD, resulting in a material delay in the time it takes for the disease to progress to late forms of the disease, where vision is impacted and patient guality of life declines markedly".

The company said the participants would be followed for a further 12 months. Ellex was up 2.5 cents or 4.7 percent to 55.5 cents.

COGSTATE

Cogstate says it has raised \$4 million in a placement at 17.5 cents a share to Australian Ethical Investment.

Cogstate said the funds would be used "to strengthen [its] balance sheet".

The company said that Taylor Collison was the advisor to the placement and would be paid a fee of 2.5 percent of the funds raised, or \$100,000.

Cogstate was in a trading halt and last traded at 15.5 cents.

<u>CELLMID</u>

Cellmid has told an ASX aware query that a 29.4 percent jump in share price before its sales revenue announcement on July 4, 2019 did not indicate a confidentiality breach. The ASX said that between July 1 and July 4, 2019 Cellmid's share price rose 29.4 percent from 17 cents to 23 cents a share, there was "a significant increase" in the volume of securities traded and asked when Cellmid first became aware of the sales information. The company said it became aware of the increase in sales after hours on July 3, 2019, verified the sales on the morning of the July 4.

Cellmid made the announcement at 2.49pm on July 4.

Cellmid said it "does not believe the trading [on July 2 and 4] ... indicated that confidentiality may have been lost having only known the final sales themselves after hours on July 3 and the verified Australia dollar value on Thursday July 4". Cellmid fell half a cent or two percent to 24.5 cents.

<u>SOMNOMED</u>

Somnomed says it has treated 500,000 patients worldwide with its Somnodent mouthguard anti-snoring device.

Somnomed chief executive officer Neil Verdal-Austin said the 500,000th patient was a "milestone" and said the company was a leader in oral appliances for sleep apnoea. Somnomed was up one cent or 0.7 percent to \$1.55.

ANTEO DIAGNOSTICS

Anteo says it has an agreement with an unnamed battery anode producing company for the improvement of lithium ion battery energy density.

Anteo said the agreement included a focus on its silicon composites and the agreement included a joint material development program with shared material, test data and knowledge to develop high performing battery products.

Anteo chief executive officer Harley Frankfurt said the agreement was "a clear endorsement of Anteo's proprietary surface chemistry technology and its appeal to globally recognized companies".

Anteo said it was commercializing molecular adhesives and silicon composites for the life sciences, diagnostics, and medical device markets.

Anteo was up 0.2 cents or 15.4 percent to 1.5 cents with 4.7 million shares traded.

<u>ADALTA</u>

UBS Group, and its related bodies corporate, has become a substantial shareholder in Adalta with 8,410,633 shares or 5.12 percent of the company.

UBS said it bought and sold shares between May 29 and July 3, 2019, acquiring 3,340,526 shares for \$501,079 or 15 cents a share on July 3.

In May and June, Adalta said it raised \$5 million in an oversubscribed placement and \$2 million in a one-for-8.8 rights issue, respectively (BD: May 23, June 14, 2019). Adalta was up one cent or 6.45 percent to 16.5 cents.

GI DYNAMICS

Crystal Amber Fund says it has increased its holding in GI Dynamics from 467,864,215 shares (48.78%) to 923,393,914 shares (65.15%).

The Guernsey-based Crystal Amber said that between June 18 and July 3, 2019 it acquired 455,529,704 shares for \$8,585,354 or an average of 1.88 cents a share through on-market purchase and convertible notes.

GI Dynamics was up 0.2 cents or 6.7 percent to 3.2 cents.

EMVISION MEDICAL DEVICES

Emvision says that 300,000 options exercisable at 35 cents each by December 31, 2021, will be released from escrow on July 17, 2019.

Emvision's most recent appendix 3B new issue announcement said it had 40,789,399 shares available for trading, of which 1,300,000 were held in voluntary escrow until June 13, 2020.

The company said there were 16,789,351 shares, 6,000,000 performance rights and 5,000,000 options exercisable at 35 cents each by December 31, 2021, held in escrow until December 13, 2020.

Emvision fell two cents or 4.8 percent to 40 cents.