



Biotech Daily

Wednesday March 4, 2020

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: ALTERITY UP 8%; IMUGENE DOWN 11.5%**
- * **NEUREN, ACADIA FDA TROFINETIDE RETT 'RARE PAEDIATRIC' STATUS**
- * **STARPHARMA EXPANDS OKAMOTO VIVAGEL CONDOM LICENCE**
- * **RACE REQUESTS PLACEMENT TRADING HALT**
- * **BOTANIX DATA ANALYSIS: 'BTX1503 BEATS VEHICLE FOR ACNE'**
- * **SERVATUS: HUGH ALSOP DIRECTOR, DR JESSICA ALLEGRETTI PI**

MARKET REPORT

The Australian stock market fell a further 1.71 percent on Wednesday March 4, 2020, with the ASX200 down 110.3 points to 6,325.4 points.

Seven of the Biotech Daily Top 40 stocks were up, 29 fell and four traded unchanged. All three Big Caps fell.

Alterity (Prana) was the best, up 0.1 cents or 7.7 percent to 1.4 cents with 652,472 shares traded. Dimerix and Patrys climbed more than six percent; Avita improved 4.2 percent; Amplia and Resonance were up more than three percent; with Paradigm one percent.

Imugene led the falls, down 0.3 cents or 11.5 percent to 2.3 cents, with 24.1 million shares traded.

Opthea lost 10 percent; Cyclopharm fell 8.2 percent; Impedimed and Oncosil were down more than seven percent; LBT, Nanosonics, Proteomics and Volpara retreated more than six percent; Immutep, Osprey and Uscom were down more than five percent; Antisense, Compumedics, Cochlear, Ellex, Genetic Signatures, Orthocell, Polynovo, Prescient, Pro Medicus and Telix fell more than four percent; Medical Developments and Pharmaxis were down more than three percent; Clinuvel, CSL and Neuren shed more than two percent; Mesoblast, Next Science and Resmed were down more than one percent; with Cynata and Starpharma down by less than one percent.

NEUREN PHARMACEUTICALS

Neuren says the US Food and Drug Administration has awarded Acadia rare paediatric disease designation for its US study of trofinetide for Rett syndrome.

In 2018, Neuren said the San Diego, California-based Acadia Pharmaceuticals had paid it \$US10 million (\$A13.6 million) in upfront fees as part of an up to \$630 million North American licence agreement for trofinetide (BD: Aug 7, 22, 2018).

Last October, the company said Acadia had begun the 180-patient, phase III 'Lavender' trial of trofinetide for Rett syndrome to assess efficacy and safety compared to a placebo for 12 weeks on females between five and 20 years of age (BD: Oct 31, 2019).

Neuren said patients would be eligible to continue treatment for 40 weeks to provide longer-term safety data, as part of the Lilac study.

Today, the company said the sponsor of the Lavender program would be eligible for a priority review voucher, which could be used to obtain FDA review of a new drug application for another product in an expedited period of six months or could be sold for use by another company.

Neuren said that under its licence agreement with Acadia, it would receive one third of the market value of a priority review voucher.

The company said that in 2019, two vouchers were sold for \$US105 million (\$A159.2 million) and \$US95 million (\$A144.0 million).

Neuren said it expected results from the Lavender study in 2021, with potential marketing approval in 2022.

Acadia president Dr Serge Stankovic said the company was "pleased that the FDA has recognized the unmet need currently experienced by Rett patients and their families and our goal is to bring a treatment option forward as soon as possible".

Neuren fell 4.5 cents or 2.3 percent to \$1.88.

STARPHARMA HOLDINGS

Starpharma says the Japan-based Okamoto Industries has expanded its licence territory for the Vivagel condom to a further 11 Asian countries.

Last year, Starpharma said Okamoto had launched its Vivagel condom under the Zero Zero Three brand in Japan (BD: Jun 4, 2019).

Today, the company said Okamoto would now have marketing rights in South Korea, Indonesia, Malaysia, Thailand, Singapore and the non-government China market.

In 2015, Starpharma said it had a memorandum of understanding with an unnamed Chinese company for marketing rights to China's government sector and today said that Shenyang Sky & Land Latex had the China Government rights (BD: Dec 16, 2015).

Starpharma said it would receive royalties on sales of the Vivagel condom and would receive revenue on the supply of the SPL7013 active ingredient in Vivagel.

The company said Okamoto would be responsible for regulatory submissions, marketing, development and launch obligations and other related costs.

Starpharma fell half a cent or 0.5 percent to \$1.00.

RACE ONCOLOGY

Race has requested a trading halt "pending an announcement regarding a share placement to a strategic investor".

Trading will resume on March 6, 2020 or on an earlier announcement.

Race last traded at 33 cents.

[BOTANIX PHARMACEUTICALS](#)

Botanix says further data analysis of the secondary endpoint in its 368-patient, phase II trial shows its synthetic cannabinoid BTX1503 is better than vehicle for acne.

Botanix said that a five percent strength dose of BTX1503 once a day was statistically superior to the vehicle, the same formulation without synthetic cannabidiol, across the entire study including both inflammatory and non-inflammatory lesions ($p = 0.033$).

Last October, the company said it did not meet its primary endpoint for reduction of inflammatory lesions, or pimples, at 12 weeks (BD: Oct 23, 2019).

The company said that five percent BTX1503 once daily showed a reduction of 11.8 inflammatory lesions or an average of 40.54 percent reduction, but the combined vehicle group had a reduction of 11.3 lesions or 40.15 percent, and the difference was not statistically significant.

Today, Botanix said that when both inflammatory lesions, or pimples, and non-inflammatory lesions, described as “comedones or pimples that have not yet broken through the skin and are not yet inflamed” including blackheads.

Botanix was up 0.6 cents or 7.9 percent to 8.2 cents with 2.2 million shares traded.

[SERVATUS](#)

Queensland’s Servatus says it has appointed Hugh Alsop as a non-executive director and Dr Jessica Allegretti as principal investigator for its impending trials.

The Sippy Downs, Sunshine Coast-based Servatus said that Mr Alsop had more than 22 years’ experience as a biotechnology executive and was currently the chief executive officer of Kinosis Therapeutics, a director of Dimerix and chief executive officer of Hatchtech and was previously an executive at Acrux, Phosphagenics, Sigma and Faulding.

Mr Alsop holds a Bachelor of Science from the University of Melbourne and a Masters of Business Administration from the Melbourne Business School.

The company said that Dr Allegretti was a gastroenterologist and microbiome specialist at Harvard University and had been appointed as the principal investigator for its planned clinical trials in ulcerative colitis, a chronic inflammatory bowel disease (IBD).

Servatus said that Dr Allegretti would be a research and clinical adviser for the company, which aimed to deliver first line and adjunct treatments for select autoimmune, gastrointestinal and dermatological conditions.

The company said that Dr Allegretti was the director of clinical trials at Boston’s Brigham and Women’s Hospital Crohn’s and Colitis Centre.

Servatus said that Dr Allegretti held a “pre-medical” degree from New York’s Cornell University, a Doctor of Medicine from the University of Miami and a Master of Public Health from the Harvard School of Public Health.

Servatus is a private company.