



Biotech Daily

Monday March 13, 2023

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: NEUREN UP 18.5%; USCOM DOWN 10%**
- * **NEUREN UP 27% ON FDA ARCADIA DAYBUE/TROFINETIDE FOR RETT OK**
- * **AUSTRALIA BIOTECH EXPOSURE TO SILICONE VALLEY BANK COLLAPSE**
- * **OSTEOPORE RIGHTS OFFER FOR \$2.6m**
- * **BOTANIX PLEADS 'SCHULTZ, FDA, WEBINAR' TO ASX 28% PRICE QUERY**
- * **RACE APPOINTS CROs FOR ZANTRENE 'OBSERVATIONAL' TRIAL**
- * **GENETIC TECHNOLOGIES: GENETYPE TEST BEATS 'GOLD STANDARD'**
- * **LIVING CELL, APET DRUG DELIVERY PLATFORM TALKS**
- * **DORSAVI REQUESTS 'CAPITAL RAISING' TRADING HALT**
- * **ZELIRA REQUESTS 'CAPITAL RAISING' TRADING HALT**
- * **LHC: 'BELOW 5% OF BTC HEALTH'**
- * **AROVELLA APPOINTS DR THOMAS DUTHY CHAIR**

MARKET REPORT

The Australian stock market fell 0.5 percent on Monday March 13, 2023, with the ASX200 down 35.9 points to 7,108.8 points. Seven of the Biotech Daily Top 40 stocks were up, 23 fell, eight traded unchanged and two were untraded. All three Big Caps fell.

Neuren was the best, closing up \$1.42 or 18.5 percent at \$9.09 with 4.2 million shares traded. Alcidion was up eight percent; Oncosil climbed 6.1 percent; Imugene improved four percent; Impedimed was up 3.6 percent; Opthea rose 1.7 percent; with Nanosonics up by 0.8 percent.

Uscom led the falls, down 0.5 cents or 10.4 percent to 4.3 cents, with 118,914 shares traded. Dimerix and Prescient lost eight percent or more; Pharmaxis fell 7.7 percent; Avita and Paradigm were down more than five percent; Amplia, Mesoblast and Patrys fell four percent or more; Cyclopharm, Proteomics and Universal Biosensors were down more than three percent; Clinuvel, Emvision, Medical Developments, Resmed, Starpharma and Telix shed more than two percent; Actinogen, Cochlear, CSL, Orthocell and Volpara were down one percent or more; with Genetic Signatures, Polynovo and Pro Medicus down by less than one percent.

NEUREN PHARMACEUTICALS

Neuren says North America partner Acadia Pharmaceuticals has US Food and Drug Administration approval for Daybue, or trofinetide, for Rett syndrome.

Neuren said that approval was in adults and children two years of age and older.

Biotech Daily believes this is the first FDA approval for an Australian drug since Telix's Illucix for prostate cancer imaging in December 2021 (BD: Jan 16, 2022).

Other recent Australian-developed drugs approved by the FDA include Perth's Peron Institute's casimersen, eteplirsen and golodirsen for Duchenne muscular dystrophy in 2021; Pharmaxis Bronchitol for cystic fibrosis and Hatchtech's Xeglyze for head lice and eggs in 2020, Clinuvel's Scenesse for erythropoietic protoporphyria (EPP) in 2019 and Medicines Development for Global Health (MDGH) moxidectin for river blindness or onchocerciasis in 2018 (BD: Jun 14, 2018; Oct 9, 2019; Aug 3, Nov 2, 2020; Apr 1, 2021).

Today, Neuren said that trofinetide was the "first and only approved treatment for Rett syndrome" and Acadia expected it to be available by the end of April 2023.

The company said the San Diego, California-based Acadia had been awarded a Rare Pediatric Disease Priority Review Voucher with the approval and it would receive \$US40 million on the first commercial sale, royalties on net sales, potential sales milestone payments and one third of the Priority Review Voucher, about \$US33 million.

Acadia said the approval was supported by the 187-patient, phase III Lavender study which showed statistically significant improvement compared to placebo on both co-primary efficacy endpoints, as measured by the change from baseline in Rett syndrome behavior questionnaire total score ($p = 0.018$) and the clinical global impression-improvement scale score ($p = 0.003$), at week 12 (BD: Dec 7, 2021).

Neuren chief executive officer Jon Pilcher said that "many people have shown great determination over the long journey to reach this historic outcome".

"The greatest has been shown by the Rett syndrome community and I am delighted for them," Mr Pilcher said.

"For Neuren, this is a transforming milestone that places us in a position to make the most of the opportunities ahead of us, as we work with the communities to make a difference in four other neurodevelopmental disorders," Mr Pilcher said.

Neuren said that it received a \$US10 million milestone from Acadia following the acceptance of the new drug application for review by the FDA and was eligible for royalties on net and milestone payments up-to US\$350 million.

The company said it had an exclusive licence with Acadia to develop and commercialize trofinetide for Rett syndrome and other indications in North America and retained all rights to trofinetide for all countries outside North America (BD: Aug 7, 2018).

Neuren said it intended to pursue registration and commercialization of trofinetide through partners and was currently advancing discussions with third parties.

Former seven-year Neuren executive chair, Dr Richard Treagus said that "what makes this accomplishment all the more remarkable is that the Neuren team designed and validated both the endpoint measurement tool for Rett syndrome, at the same time as developing and proving up a novel drug compound".

"We started with a blank sheet of paper just over 10 years ago and built every aspect in excruciating detail from the ground up," Dr Treagus said.

"Ultimately the partnership with Acadia in 2018 secured the significant funding pathway for phase III, FDA approval and market access," Dr Treagus said.

"But congratulations are in order for Prof Margaret Brimble the inventor of the compound and to Jon [Pilcher] for his terrific leadership bringing this home," Dr Treagus said.

Neuren climbed as much as \$2.07 or 27.0 percent to \$9.74 before closing up \$1.42 or 18.5 percent at \$9.09 with 4.2 million shares traded.

SILICONE VALLEY BANK

Tissue Repair says it “expects to be able to access” the \$US2.2 million (\$A3.3 million) held at the Silicon Valley Bank tomorrow.

Tissue Repair said that the Silicon Valley Bank was placed in receivership by the Federal Deposit Insurance Corporation on March 10 2023, but the US Federal Reserve and the FDIC had said: “Depositors will have access to all of their money starting Monday, March 13” US time.

EBR Systems said it did “not anticipate any financial exposure or material impact on operations resulting from [the Bank’s] closure”.

EBR said it had a banking relationship with Silicon Valley Bank, its payables were managed through a checking/operations account, which held about 0.2 percent its cash, which was within the \$US250,000 limit which was fully insured by the Federal Deposit Insurance Corporation.

Visioneering Technologies said that its deposit accounts at the Silicon Valley Bank “in excess of the insured limit (\$US250,000) are less than \$US100,000, which the company does not believe is a material portion of its cash and cash equivalents”.

Visioneering said it held the remainder of its investments at another institution.

Clinuvel Pharmaceuticals and Pro Medicus said that they had no exposure to the Silicon Valley Bank (SVB) Financial Group.

OSTEOPORE

Osteopore says it hopes to raise \$2,633,617 through a one-for-four rights offer 8.5 cents a share, a 27.4 percent discount to the 10-day volume weighted average price.

Osteopore said shareholders would also be issued one option for each share bought, exercisable at 22.5 cents within three years from issue

The company said the funds would be used to support sales momentum, develop and launch new products, secure regulatory clearances, help with partnerships and acquisitions and provide general working capital.

Osteopore said that the record date for the rights offer was March 16, it would open on March 21 and close on April 4, 2023.

The company said that Melbourne’s Cadmon Advisory was the lead manager for the offer. Osteopore fell 2.7 cents or 23.5 percent to 8.8 cents.

BOTANIX PHARMACEUTICALS

Botanix 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, but noted its upcoming FDA review and webinar.

In the query, the ASX said that the company’s share price rose 2.3 cents, or 28.05 percent from an intraday intra-day low of 8.2 cents to an intra-day high of 10.5 cents on March 10, 2023, and noted a “significant increase” in trading volume.

Botanix said the previously announced US Food and Drug Administration (FDA) review of its sofipronium bromide topical gel for excessive underarm sweating was scheduled for completion by March 31, 2023 and was considered to be a “significant milestone event” (BD: Dec 8, 2022).

The company said it conducted a webinar on March 8 that provided “new insights into the competitive and market situation and opportunities to access patients through digital outreach” which could also explain the recent trading in its shares.

Botanix was unchanged at 10 cents with 11.5 million shares traded.

RACE ONCOLOGY

Race says has hired two contract research organizations for its 50-breast cancer patient “observational” trial of heart damage caused by chemotherapy.

Race said it would pay \$422,390 to Resolutum Global for data management and biostatistics service, \$658,297 to Beyond Drug Development for clinical site management and monitoring, safety management reporting and clinical study report development services and \$206,929 to the New South Wales Regional Biospecimen and Research Services for patient sample kit production, processing and sample storage services.

The company said that the study would recruit up to 50 patients being treated with doxorubicin and cyclophosphamide that have two or more cardiovascular risk factors. Race said that data from the study would be used to design a subsequent phase I/IIb interventional trial that could help patients avoid heart damage associated with doxorubicin and cyclophosphamide chemotherapy regimes.

Race was up seven cents or 3.5 percent to \$2.06.

GENETIC TECHNOLOGIES

Genetic Technologies says its Genetype breast cancer risk assessment test performs better than the BCRAT “gold-standard model”.

Genetic Technologies said a research article, titled ‘Validation of an abridged breast cancer risk prediction model for the general population’, was published in the journal Cancer Prevention Research, with the abstract available at: <https://bit.ly/3ZZKM0d>.

The company said its study with the University of Melbourne’s Prof John Hooper used a prospective cohort of more than 200,000 women from the UK Biobank.

Genetic Technologies said the Genetype breast cancer risk test “not only put more women into an increased risk category but also demonstrated women in this category developed breast cancer at a higher incidence”.

Genetic Technologies was up 0.1 cents or 33.3 percent to 0.4 cents with 1.75 million shares traded.

LIVING CELL TECHNOLOGIES

Living Cell says it is in discussion with Apet Holding BV to use its controlled-release drug delivery platform for its NTCell pig choroid cell Parkinson’s disease treatment.

Living Cell said no agreement had been reached and potential transactions could include, but were not limited to, a partnership, collaboration and licensing agreements, or the acquisition of the Ijsselstein, Netherlands-based Apet.

The company said it was undertaking due diligence on Apet’s intellectual property and patents.

Living Cell was unchanged at one cent.

DORSAVI

Dorsavi says it has requested a trading halt pending an announcement “concerning a proposed capital raising”.

Trading will resume on March 15, 2023, or on an earlier announcement.

Dorsavi last traded at 1.2 cents.

ZELIRA THERAPEUTICS

Zelira says it has requested a trading halt pending an announcement by the company “in relation to a capital raising”.

Trading will result on March 15, 2023, or on an earlier announcement.

Zelira last traded at \$1.00.

BTC HEALTH

Sydney’s LHC Capital says it has ceased its substantial holding in BTC, selling 241,369 shares at 2.34 cents a share on March 8, 2023.

Last year, in a notice signed by LHC chief executive officer Stephen Aboud, the company said it held 15,705,222 shares or 5.57 percent (BD: Nov 4, 2022).

According to BTC’s annual report, the company had 281,846,354 shares on offer and Biotech Daily calculates that LHC retains 15,463,853 shares or 5.49 percent.

BTC fell 0.2 cents or 7.7 percent to 2.4 cents.

AROVELLA THERAPEUTICS

Arovella says it has appointed Dr Thomas Duthy as its non-executive chair, replace interim chair Dr Elizabeth Stoner, effective from March 13, 2023.

Arovella said Dr Duthy had more than 18 years of financial market and board experience, and was the founder of corporate advisor and investor relation service Nemean Group.

The company said Dr Duthy was Sirtex Medical’s head of corporate development and investor relations and was currently an executive director of Invex and Neurotech.

Arovella said Dr Duffy would be issued 2,250,000 shares worth \$90,000 or four cents a share in lieu of directors fees, to be released from voluntary escrow after March 13, 2024.

Arovella was unchanged at 3.5 cents with 3.8 million shares traded.