Biotech Daily

Friday January 22, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: KAZIA UP 9%; ANTISENSE DOWN 9%**

*** CYCLOPHARM: SNMMI WANTS FDA TECHNEGAS COVID-19 FAST-TRACK**

*** IMMUTEP: GLAXOSMITHKLINE ENDS GSK2831781 (IMP731) COLITIS TRIAL**

*** SDI H1 SALES DOWN 8% TO $37m, PROFIT UP 31% TO $4.6m**

*** NUHEARA H1 RECEIPTS UP 292% TO $5.3m**

*** GENETIC TECHNOLOGIES $8.5m US PLACEMENT**

*** PHARMAUST'S EPICHEM WINS $200k ELECTRONIC WASTE GRANT**

*** PAINCHEK INFANT TRIAL RESULTS 'SUPPORT APPROVAL'**

*** SIMAVITA BUYS-BACK, CANCELS $862k CDIs**

*** ECOFIBRE: ROBIN SHELDON JOINT CO-SEC, GENERAL COUNSEL**

MARKET REPORT

The Australian stock market fell 0.34 percent on Friday January 22, 2021, with the ASX200 down 23.3 points to 6,800.4 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 17 fell, eight traded unchanged and one was untraded.

Kazia was the best, up 12 cents or 9.4 percent to $1.40, with 805,428 shares traded. Oncosil climbed eight percent; Patrys was up 6.9 percent; Alterity improved 5.7 percent; LBT was up 4.35 percent; Telix and Universal Biosensors were up more than three percent; CSL and Proteomics rose two percent or more; Amplia and Genetic Signatures were up more than one percent; with Cochlear, Medical Developments, Polynovo, Starpharma and Volpara up by less than one percent.

Antisense led the falls, down two cents or 8.7 percent to 21 cents, with 6.6 million shares traded, followed by Optiscan down eight percent to 11.5 cents, with 65,333 shares traded. Immutep and Resonance retreated more than five percent; Dimerix, Imugene and Neuren fell more than four percent; Cynata, Paradigm and Pharmaxis shed more than two percent; Avita, Clinuvel, Mesoblast and Next Science were down more than one percent; with Nanosonics, Opthea, Pro Medicus and Resmed down by less than one percent.

CYCLOPHARM

Cyclopharm says the Society of Nuclear Medicine and Molecular Imaging has called on the US Food and Drug administration to expedite the approval of Technegas.

Last year, Cyclopharm said its phase III Technegas lung imaging trial closed early, after data from 200 patients met the primary efficacy endpoint, and last week said it hoped for FDA approval of its lung ventilation imaging agent for pulmonary embolism by July 2021 (BD: Sep 15, 2020; Jan 17, 2021).

Today, the company said the Reston, Virginia-based Society of Nuclear Medicine and Molecular Imaging (SNMMI) was a 16,000-member, scientific and professional organization which promoted the science, technology and practical application of nuclear medicine and molecular imaging.

In a letter to the FDA, the Society said Technegas was safer, in the context of Covid-19, for use in ventilation/perfusion (V/Q) lung scans, which could be required to diagnose lung disease and pulmonary embolism when x-rays and alternative diagnostic routes could not.

The SNMMI said it previously released a statement which outlined the concerns of the spread of Covid-19 to staff and patients during the ventilation portion of the V/Q lung scan, given that the administration of two approved radiopharmaceuticals used in ventilation imaging released aerosolized partials.

The Society said the particles might increase the risk of exposure to Covid-19 for imaging technicians required to be in the room throughout the V/Q study.

The SNMMI said that Technegas, as opposed to other ventilation scanning technologies "doesn't release aerosolized particles during the ventilation scan [and] is therefore safer to utilize during the Covid-19 pandemic".

The Society said Technegas could provide an alternative to radioactive aerosolized particles that was "less expensive and available daily".

Cyclopharm said its FDA Technegas application was under the standard review period and the FDA had scheduled "an onsite pre-approval audit of the company's manufacturing facility during the week commencing March 29, 2021".

Cyclopharm managing-director James McBrayer the company was "in active and co-operative dialogue" with the FDA regarding its approval and grateful for the support from the US nuclear medicine and molecular imaging community.

"We understand the urgency behind the SNMMI's request for an expedited approval of the use of Technegas in the US and will continue to work proactively with the FDA," he said.

Cyclopharm was in a trading halt for a placement and last traded at $2.94.

IMMUTEP, GLAXOSMITHKLINE

Immutep says licencing partner Glaxosmithkline has discontinued its phase II trial of GSK2831781 for ulcerative colitis and will evaluate the drug for other uses.

In 2019, Immutep said announced the trial and said GSK2831781 was an anti-lymphocyte activation gene-3 (LAG-3) antibody derived from its IMP731 (BD: Sep 23, 2019).

Today, the company said Glaxosmithkline had terminated the trial based on the results of an interim analysis and was analyzing the efficacy and safety of GSK2831781 to determine the next steps in the drug's development program.

Immutep said GSK2831781 was licenced to Glaxosmithkline in 2010 and in a phase I study of psoriasis showed evidence of efficacy (BD: Jan 27, 2015).

Immutep said its agreement with Glaxosmithkline remained in place and it was eligible to receive up-to GBP54 million ($A95.6 million) in milestone payments as well as single-digit tiered royalties for the commercialization of GSK2831781.

Immutep fell 2.5 cents or 5.8 percent to 40.5 cents with 4.5 million shares traded.

SDI (FORMERLY SOUTHERN DENTAL INDUSTRIES)

SDI says sales for the six months to December 31, 2019 fell 8.0 percent to $36.8 million, with unaudited profit after tax up 30.6 percent to $4.6 million.
SDI said sales revenue from its dental equipment and dental aesthetics, amalgam and whitening products increased by 43.2 percent in the domestic Australian market but fell 29.7 percent in direct exports, while increasing 12.6 percent in Europe, 9.4 percent in North America, 3.1 percent in Brazil, and falling 41.7 percent in the UK.
The company said sales recovered from the impacts of Covid-19 due to “pent up demand … [but] with product supply to many overseas markets continuing to be challenging”.
SDI was up two cents or 2.5 percent to 82 cents.

NUHEARA

Nuheara says its customer receipts from sales of its hearing and sound filtering units for the six months to December 31, 2020 rose 292.4 percent to $5,344,000.
Nuheara said it had record receipts for the three months to December 31, 2020 of $4,812,000, up 428.8 percent compared to the previous corresponding period.
The company said it had cash and cash equivalents of $2,400,000 at December 31, 2020 but completed an $11.5 million placement on January 7 (BD: Jan 17, 2021).
Nuheara was up 0.2 cents or 4.35 percent to 4.8 cents with 15.5 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says it has “conditional agreements” to raise $US6.56 million ($A8.46 million) in American depositary shares (ADSs) at $US5.25 each.
Genetic Technologies said each ADS represented 600 Australian shares, with the price implying a value of 1.125 Australian cents each.
Last year, the company said it raised a total of $US16.34 million ($A21.09 million) in four placements through HC Wainwright at prices ranging from $US1.75 per ADS (0.48 Australian cents per Australian share) to $US5.00 per ADS (1.2 Australian cents per Australian share) (BD: Apr 6, 21; May 27; Jul 21, 2020).
Today, Genetic Technologies said the funds would be used to distribute products in the US and Europe, for research and development of its polygenic risk tests, preparation for its Covid-19 risk test, introduction of germline genetic testing division and working capital.
The company said HC Wainwright was the agent to the placement.
Genetic Technologies was up 0.3 cents or 33.3 percent to 1.2 cents with 397.0 million shares traded.

PHARMAUST

Pharmaust says Western Australia has granted $200,000 to its synthetic and medicinal chemistry subsidiary Epichem to convert electronic waste into useful end products.
Pharmaust said the grant was awarded through the Western Australian Government New Industries Fund to finance the use of oxidative hydro-thermal dissolution technology to recover metals and produce useful chemicals and other products, reducing the amount of electronic waste ending up in landfill.
Epichem chief executive officer Colin La Galia said that “the technology has the potential to deliver significant benefits across a range of industries; supporting the economy and positively impacting the environment”.
Pharmaust was up 0.2 cents or two percent to 10 cents with one million shares traded.

PAINCHEK

Painchek says results from a 100-patient trial of its smartphone pain assessment and monitoring application for infants supports its regulatory clearance applications.

In 2019, Painchek said the Murdoch Children's Research Institute began a 100-patient trial to of its Painchek Infant Face-Only application at Melbourne's Royal Children's Hospital, which assessed infants undergoing painful procedures within the emergency department (BD: Jul 2, 2019).

Today, the company said that with the results it was on schedule for Australian Therapeutic Goods Administration and Conformité Européenne (CE) mark approvals by July 2021.

Painchek said the study findings showed that Painchek Infant has "excellent correlation" with the Revised Neonatal Facial Coding System and the Observer Visual Analogue Scale.

The company said detailed results of the study would be made available following the peer-review and publication in a scientific journal.

Painchek was up 0.3 cents or 4.2 percent to 7.4 cents with five million shares traded.

SIMAVITA

Simavita says it has bought-back 46,587,231 Chess Depositary Interests (CDIs) worth $861,864 at 1.85 cents each as part of its $1,000,000 capital reduction.

In October, Simavita said it planned to delist from the ASX and fund a $1 million capital reduction to continue as an unlisted company focused on its Smartz wearable and disposable nappy technology for adults and infants (BD: Oct 30, 2020).

Earlier this week, the company said it had received shareholder approval and would delist from the ASX on February 22, 2020 (BD: Jan 20, 2020).

Today, Simavita said the re-purchased CDIs would be cancelled, and according to the company's most recent Appendix 2A application for quotation of securities, it would have 1,284,201,756 CDIs available for trading on the ASX following the cancellation.

Simavita was up 0.2 cents or 12.5 percent to 1.8 cents.

ECOFIBRE

Ecofibre says it has appointed Robin Sheldon as general counsel and joint company secretary alongside company secretary and chief financial officer Jonathan Brown.

Ecofibre said Ms Sheldon had 29 years' experience in corporate law and was previously a senior executive at the Philadelphia, Pennsylvania-based Thomas Jefferson University as well as a partner at Fox Rothschild.

Ecofibre fell three cents or 1.6 percent to $1.87.