

Biotech Daily

Monday January 30, 2023

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: POLYNOVO UP 4%; IMPEDIMED DOWN 13%
- * PRO MEDICUS, SAMARITAN \$12m 3 VISAGE SYSTEMS DEAL
- * MTP CONNECT \$6m FOR INDIGENOUS DIABETES, C-V DISEASE
- * SOMNOMED H1 RECEIPTS UP 11% TO \$38.8m
- * ALCIDION H1 RECEIPTS UP 15% TO \$18.8m
- * GENETIC SIGNATURES H1 RECEIPTS DOWN 47.5% TO \$11.8m
- * NEXT SCIENCE RECEIPTS UP 12% TO \$15m
- * CANN GROUP H1 RECEIPTS UP 78% TO \$5.8m
- * IMPEDIMED H1 RECEIPTS UP 10% TO \$5.6m
- * GENETIC TECHNOLOGIES H1 RECEIPTS UP 68% TO \$4.5m
- * RHINOMED H1 RECEIPTS UP 3.9% TO \$4m
- * UNIVERSAL BIOSENSORS RECEIPTS UP 1% TO \$4m
- * UNIVERSAL BIOSENSORS LAUNCHES WINE FRUCTOSE TEST
- * CYNATA: US ETHICS APPROVAL FOR CYP-001 FOR GVHD TRIAL
- * OPTISCAN, PROLUCID TO DEVELOP AI ALGORITHMS
- * ALTERITY: 'ATH434 NEURO-PROTECTIVE FOR PARKINSON'S, IN MICE'
- * EMYRIA DOSES 1st MARIJUANA EMD-RX5 FOR DISTRESS TRIAL PATIENT
- * CRESO LA PLATA LOANS: BUYS ABBY & FINN
- * PATRYS RECEIVES \$3.35m FEDERAL R&D TAX INCENTIVE
- * ZELIRA RECEIVES \$1.1m FEDERAL R&D TAX INCENTIVE
- * REGENEUS REQUESTS 'KYOCERA' TRADING HALT
- * JM FINANCIAL, NO PLAN B REDUCE TO 14.3% OF MACH7
- * MERCHANT FUNDS TAKES 9.25% OF AROVELLA

MARKET REPORT

The Australian stock market fell 0.16 percent on Monday January 30, 2023, with the ASX200 down 12.1 points to 7,481.7 points.

Eleven of the Biotech Daily Top 40 stocks were up, 18 fell, nine traded unchanged and two were untraded.

Polynovo was the best, up 10 cents or 4.2 percent to \$2.49, with 2.5 million shares traded.

Avita, Immutep and Resonance climbed more than three percent; Telix rose 2.9 percent; Clinuvel, Cochlear, Mesoblast, Opthea, Pro Medicus and Volpara were up more than one percent; with Emvision up by 0.3 percent.

Impedimed led the falls, down 0.9 cents or 13.2 percent to 5.9 cents, with 6.5 million shares traded.

Patrys lost 9.4 percent; Alcidion, Resmed, Starpharma and Universal Biosensors retreated more than six percent; Prescient was down 5.9 percent; Actinogen and Genetic Signatures fell more than four percent; Antisense, Imugene, Micro-X and Orthocell were down more than three percent; Medical Developments, Neuren, Nova Eye and Proteomics shed two percent or more; Nanosonics and Next Science were down more than one percent; with CSL down by 0.6 percent.

PRO MEDICUS

Pro Medicus says it has a \$12 million, eight-year contract with the Corvallis, Oregon-based integrated delivery network Samaritan Health Services.

Pro Medicus said that Samaritan had five hospitals in the mid-Willamette Valley and central Oregon Coast and would employ the company's internet cloud-engineered Visage 7 Enterprise Imaging Platform, including Visage 7 Open Archive and Visage 7 Workflow modules, "providing a unified diagnostic imaging platform across the network".

The company said that Samaritan had "opted for a fully cloud-based solution, a trend that has continued to spread across the North American healthcare [information technology] market".

Pro Medicus said that planning for the rollout was to begin immediately, with initial use targeted for by the end of 2023.

Pro Medicus chief executive officer Dr Sam Hupert said that Samaritan joins a growing list of integrated delivery network (IDN) clients "and will reinforce our strong presence in the Northwest region of the United States".

"IDNs are the largest market segment in North America, and this is our fifth material IDN contract in the last 12 months," Dr Hupert said.

"This deal represents another 'full-stack' Visage 7 solution comprising all three Visage products namely viewer, workflow and archive, and builds on our increasing momentum in the IDN space," Dr Hupert said.

"It also reinforces our view that our platform is equally suited to mid-sized IDNs as it is to the larger ones, enabling us to address multiple segments of this important market," Dr Hupert said.

Pro Medicus was up 76 cents or 1.2 percent to \$65.86 with 157,182 shares traded.

MTP CONNECT

MTP Connect says it has opened a \$6 million funding round for projects to benefit indigenous Australians living with diabetes and cardiovascular disease.

MTP Connect said that the Targeted Translation Research Accelerator program had a new funding round to support projects that addressed the unmet health and medical needs of Aboriginal and Torres Strait Islander peoples in Australia.

MTP Connect chief executive officer Stuart Dignam said the funding aimed to have a lasting impact on the health and wellbeing of Indigenous communities.

"Aboriginal and Torres Strait Islander peoples are significantly disproportionately affected by diabetes and cardiovascular disease at up to four times the rate of Australia's wider population," Mr Dignam said.

MTP Connect said applications would close on April 28, 2023 and for more information go to: https://www.mtpconnect.org.au/programs/TTRA/ResearchProjectsRound3.

To register for an information webinar on February 6, 2023 at 12:30pm (AEDT) go to: https://mtpconnect.zoom.us/webinar/register/WN_iyr3mVdT2ipE1SqTbjw_w.

SOMNOMED

Somnomed says receipts from customers for the six months to December 31, 2022 was up 11.1 percent to \$38,765,000 compared to the prior corresponding period. Somnomed said its receipts from customers for its obstructive sleep apnea oral devices for the three months to December 31, 2022 was up 13.2 percent to \$21,162,000, compared to the previous corresponding period.

The company said it was \$1,230,000 cash flow positive with cash and cash equivalents of \$16,875,000 compared to \$17,571,000 at December 31, 2021.

Somnomed fell three cents or 2.3 percent to \$1.26.

ALCIDION

Alcidion says receipts from customers for the six months to December 31, 2022 was up 14.7 percent to \$18,819,000, compared to the prior corresponding period.

Alcidion said its receipts from customers for its patient management software for the three months to December 31, 2022 fell 30.8 percent to \$6,813,000, compared to the previous corresponding period.

The company said it had a \$4,472,000 cash burn for the three months to December 31, 2022, with cash and cash equivalents of \$11,868,000 compared to \$18,938,000 at December 31, 2021.

Alcidion fell one cent or 6.25 percent to 15 cents with 4.8 million shares traded.

GENETIC SIGNATURES

Genetic Signatures says receipts for the six months to December 31, 2022 fell 47.5 percent to \$11,764,000 compared to the prior corresponding period.

Genetic Signatures said its receipts from customers for its 3base Easyscreen Sars-Cov-2 testing kits for the three months to December 31, 2022 were down 67.6 percent to \$3,917,000 compared to the previous corresponding period, but non=Covid related products were up 49 percent to \$3.4 million.

The company said it had a \$2,977,000 cash burn with cash and cash equivalents of \$26,810,000 at December 31, 2022 compared to \$37,496,000 at December 31, 2021. Genetic Signatures fell 4.5 cents or 4.6 percent to 92.5 cents.

NEXT SCIENCE

Next Science says customer receipts for the year to December 31, 2022 rose 12.0 percent to \$US10,657,000 (\$A15,024,000) compared to the prior corresponding period.

Next Science said that receipts from sales of its wound treatments for the three months to December 31, 2022 fell 0.95 percent to \$US2,919,000 compared to the previous corresponding period.

The company said it had a cash burn for the three months of \$US2,779,000 with cash and cash equivalents of \$US5,111,000 at December 31, 2022 compared to \$US7,368,000 at December 31, 2021.

Next Science fell one cent or 1.5 percent to 66 cents.

CANN GROUP

Cann Group says receipts from customers for the six months to December 31, 2022 was up 77.7 percent to \$5,758,000 compared to the prior corresponding period.

Cann Group said its receipts from customers for its medical marijuana products for the three months to December 31, 2022 was up 87.75 percent to \$3,325,000, compared to the previous corresponding period.

The company said it had a \$3,900,000 cash burn with cash and cash equivalents of \$7,240,000 compared to \$10,765,000 at December 31, 2021.

Cann Group was unchanged at 19 cents.

IMPEDIMED

Impedimed says receipts from customers for the six months to December 31, 2022 was up 9.9 percent to \$5,571,000 compared to the prior corresponding period.

Impedimed said that receipts from sales of its Sozo bioimpedance spectroscopy devices for the three months to December 31, 2022 rose 8.6 percent to \$2,828,000, compared to the previous corresponding period.

The company said it had a cash burn for the three months of \$6,475,000 with cash and cash equivalents of \$26,197,000 at December 31, 2022 compared to \$50,807,000 at December 31, 2021.

Impedimed fell 0.9 cents or 13.2 percent to 5.9 cents with 6.5 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says revenue for the six months to December 31, 2022 was up 67.5 percent to \$4,455,000 compared to the prior corresponding period.

Genetic Technologies said its receipts from customers for its Genetype and Easy-DNA cancer predictive testing tools for the three months to December 31, 2022 were up 32.6 percent to \$2,399,000 compared to the previous corresponding period.

The company said it had a \$2,810,000 cash burn with cash and cash equivalents of \$5,045,000 at December 31, 2022 compared to \$13,509,000 at December 31, 2021. Genetic Technologies was unchanged at 0.3 cents.

RHINOMED

Rhinomed says receipts from customers for the six months to December 31, 2022 fell 3.9 percent to \$3,971,000, compared to the prior corresponding period.

Rhinomed said its receipts from customers for its Rhinoswab, Rhinoswab Junior and Mute nasal dilators for the three months to December 31, 2022 was up 2.5 percent to \$2,593,000, compared to the previous corresponding period.

The company said it had a \$1,340,000 cash burn with cash and cash equivalents of \$3,666,000 compared to \$1,636,000 at December 31, 2021.

Rhinomed fell on cent or 9.1 percent to 10 cents.

UNIVERSAL BIOSENSORS

Universal Biosensors says receipts from customers for the year to December 31, 2022 was up 1.1 percent to \$4,024,000 compared to the prior corresponding period. Universal Biosensors said that receipts from sales of its blood glucose monitoring products and wine biosensors for the three months to December 31, 2022 fell 53.5 percent to \$590,000 compared to the previous corresponding period. The company said it had a cash burn for the three months of \$738,000 with cash of \$26,825,000 at December 31, 2022 compared to \$18,099,000 at December 31, 2021. Universal Biosensors fell two cents or 6.25 percent to 30 cents.

UNIVERSAL BIOSENSORS

Universal Biosensors says it has launched its fructose bio-sensor test, the fourth test on the Sentia wine testing platform.

Universal Biosensors aid it had also relaunched its glucose test, "the partner test used with fructose to measure total residual sugar during the winemaking process".

The company said that the ability to monitor and measure both glucose and fructose concentrations at the barrel would allow wine makers to more accurately determine an endpoint for fermentation.

Universal Biosensors chief executive officer John Sharman said the company estimated the market for total sugars to be more than \$160 million a year.

"Whilst we completed work on the glucose biosensor in the second half of 2022, the measurement of glucose without fructose is not meaningful for winemakers and Sentia sales were negatively impacted by the delay of fructose," Mr Sharman said.

CYNATA THERAPEUTICS

Cynata says that US central institutional research board provider Advarra Inc has approved its 60-patient, phase II trial of CYP-001 for acute graft-versus-host disease Last year Cynata said the US Food and Drug Administration has cleared its investigative new drug application for the trial, titled 'A Multicenter, Randomized, Double-blind, Placebo-Controlled Phase II Study to Investigate the Efficacy and Safety of CYP-001 in Combination with Corticosteroids vs Corticosteroids Alone for the Treatment of High-Risk Acute Graft Versus Host Disease' (BD: May 26, 2022).

Today the company said it was finalizing contractual and logistic arrangements with individual sites for patient recruitment, which was expected to begin "in the coming few months" with primary evaluation of data in 2024.

Cynata was unchanged at 31 cents.

OPTISCAN IMAGING

Optiscan says it will work with Prolucid Technologies to develop artificial intelligence algorithms and telepathology workflows for its confocal laser endo-microscopes. Optiscan said that the up-to 24-month project, with the Mississauga, Ontario-based Prolucid, would take images from its platform technology to display results of an artificial intelligence (AI) algorithm to clinicians for immediate decision-making during clinical workflows.

The company said that the application would be used by healthcare professionals in a variety of hospital and clinical settings, with a focus on oral imaging and cancer detection in the first instance.

Optiscan said the partnership would "further enhance the clinical capability of [its] technology, with the goal of developing a software as a medical device application that would support image collection, processing, and tissue analytics to detect the presence of precancerous and cancerous cells.

Optiscan managing-director Dr Camile Farah said that the development of artificial intelligence algorithms using the company's confocal microscopes "supports our vision to be at the forefront of enabling immediate, informed clinical decisions for healthcare professionals globally using digital microscopy".

"We are delighted to be partnering with Prolucid Technologies on this cutting-edge innovation project, which will help clinicians achieve the best possible patient outcomes through the earlier detection, diagnosis and treatment of cancer," Dr Farah said. Optiscan was unchanged at 12.5 cents.

ALTERITY THERAPEUTICS

Alterity says that ATH434 is neuro-protective in a genetic mouse model for Parkinson's disease.

Alterity said that the research, titled 'ATH434 Rescues Pre-motor Hyposmia in a Mouse Model of Parkinsonism' was published in the journal Neurotherapeutics and was available at: https://link.springer.com/article/10.1007/s13311-022-01300-0.

The company said that the study assessed the impact of ATH434 on motor and non-motor deficits in mice with genetically-induced Parkinson's disease and showed that, ATH434 "was neuroprotective in a genetic model of Parkinson's disease".

Alterity said that Parkinson's disease was a progressive neuro-degenerative disorder that caused slow or abnormal movements of the body and non-motor features that contribute significantly to morbidity and reduced quality of life.

The company said that hyposmia was a reduced sensitivity to odor and was an early and common non-motor symptom of that preceded the typical motor symptoms by several years, occurring in about 90 percent of early-stage cases of Parkinson's disease. Alterity said that the study found that ATH434 prevented a loss of smell in the younger mice and rescued it in older mice.

The company said the study showed that ATH434 prevented the development of motor impairment in older animals, which was associated with a reduction in iron levels and preservation of neurons in the substantia nigra, the brain region affected in Parkinson's. Alterity said the data supported other studies indicating that ATH434 had a beneficial effect on the motor and non-motor symptoms in animal models of Parkinson's disease. Alterity chief executive officer Dr David Stamler said that "efficacy in yet another model of Parkinson's disease adds to the weight of evidence supporting the potential of ATH434 to address the underlying pathology of Parkinson's disease and related disorders". Alterity was unchanged at one cent with 1.7 million shares traded.

EMYRIA

Emyria says it has dosed the first of 300 patients in its phase III trial of marijuana-based EMD-RX5 for psychological distress in adults with chronic pain.

Emyria said that dosing was "an important milestone" in the multi-site, parallel-arm, randomized, double blind, placebo-controlled study of people aged 18 to 70 years with symptoms of stress and a background of chronic pain.

The company said that participants would be randomized to one month of treatment with either 50mg EMD-RX5, 150mg EMD-RX5 or placebo.

Emyria said that the primary endpoint was to determine the effect of EMD-RX5 treatment on symptoms of psychological distress in participants with chronic pain through change in self-reported DASS-21 score from baseline to week-4.

The company said that EMD-RX5 was a solid capsule of cannabidiol (CBD) without tetrahydrocannabinol (THC) or impurities and had shown a high bioavailability in phase I trials, with the 150mg dose the maximum allowable for over-the-counter sales.

Emyria said that the trial was at nine sites and was designed to evaluate the safety and efficacy of EMD-RX5 in patients with symptoms of psychological distress such as mild anxiety and stress.

Emyria managing-director Dr Michael Winlo said that "an accessible, convenient and effective over-the-counter treatment for psychological distress could have a significant impact on the quality of life and health outcomes for patients, especially those with chronic disease".

Emyria was up half a cent or three percent to 17 cents.

CRESO PHARMA

Creso says it has a change of loan agreement La Plata Capital LLC, and will acquire Abby & Finn LLC for \$US1 million (\$A1.4 million) in scrip and \$US270,000 in notes Creso said it would repay \$US717,500 in cash and swap \$US1,282,500 for secured convertible notes valued at \$US1,282,500 of the Denver, Colorado-based La Plata's \$US2 million loan to Sierra Sage Herbs.

The company said the transaction "would significantly clean and simplify the balance sheet while providing further alignment between the two companies".

Creso said Everblu Capital Pty Ltd had waived its right to a cash fee for facilitating the transaction but would be entitled to 74,125,134 options exercisable at eight cents each within four years.

The company said that each convertible note was worth \$US67,500 with interest a flat 30 percent a year, maturing at six months and secured against its Mernova cannabis cultivation facility in Nova Scotia, with investors to receive 1,000,000 options per note, regardless of whether they convert to equity, or were repaid in cash, with the options exercisable at eight cents each and expiring in four years from approval.

Last August, Creso said it had commitments for a \$7 million placement at four cents a share to buy the Lyons, Colorado-based Sierra Sage Herbs LLC (BD: Aug 4, 2022). Today, Creso said the conversion of notes was solely at the lender's election, otherwise repayment was due six months from investment date.

The company said the conversion price was 5.0 cents a share with one attaching option for every four shares converted, exercisable at eight cents within four years.

Creso said it would acquire the Denver. Colorado-based Abby and Finn LLC, a provider of products for babies including baby wipes and nappies, which were "plant based and free of chlorine, alcohol, paraben, oil and cruelty".

Creso fell 0.1 cents or 4.55 percent to 2.1 cents with 11.3 million shares traded.

PATRYS

Patrys says it has received \$3,352,896 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Patrys said the rebate, paid to wholly-owned subsidiary Nucleus Therapeutics Pty Ltd, related to research and development expenditure for the year to June 30, 2022. Patrys fell 0.3 cents or 9.4 percent to 2.9 cents with 14.8 million shares traded.

ZELIRA THERAPEUTICS

Zelira says it has received \$1,141,000 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Zelira said the rebate related to research and development expenditure.

Zelira fell six cents or 5.7 percent to 99 cents.

REGENEUS

Regeneus has requested a trading halt "pending an announcement to the market in relation to its licence and collaboration agreement with Kyocera".

In 2021, Regeneus said Kyocera milestone payments of \$6.9 million for its stem cell platform Progenza OA for knee osteoarthritis took revenue for the six months to December 31, 2020 to \$7.1 million (BD: Mar 1, 2021; Aug 11, 28, Oct 29, 2020).

Trading will resume on February 1, 2023 or on an earlier announcement.

Regeneus last traded at 4.1 cents.

MACH7 TECHNOLOGIES

JM Financial and No Plan B Pty Ltd say they have reduced their substantial holding in Mach7 from 36,699,105 shares (15.37%) to 34,344,226 shares (14.34%).

The Melbourne-based JM and No Plan B said that between May 9, 2022 and January 17, 2023 they bought and sold shares, with the largest single sale this year, 217,760 shares for \$155,908 or 71.6 cents a share.

Mach7 fell one cent or 1.35 percent to 73 cents.

AROVELLA THERAPEUTICS (FORMERLY SUDA PHARMACEUTICALS)

The Perth-based Merchant Funds Management says it has increased its substantial holding in Arovella from 47,416,660 shares (7.89%) to 69,717,710 shares (9.25%). Merchant said that between January 31, 2022 and January 25, 2023 it bought and sold shares, acquiring 13,250,000 shares in the recent \$1.65 million placement at two cents a share (BD: Jan 22, 2023).

Arovella was up 0.1 cents or four percent to 2.6 cents.