Biotech Daily

Tuesday September 14, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PRESCIENT UP 26%; OSPREY DOWN 8%**

*** TGA APPROVES MICRO-X ROVER**

*** TELIX FILES US IND FOR TLX250 KIDNEY CANCER TRIAL**

*** TELIX: US GUIDELINES INCLUDE PSMA-PET IMAGING**

*** CRONOS TAKES CDA FOR $61m SCRIP IN MARIJUANA MERGER**

*** UNIVERSAL BIOSENSORS, PETER MAC WORK ON TN ANTIGEN TEST**

*** VGI APPOINTS GALLIPOLI FOR IVB001 NASH TRIAL**

*** DISER APPROVES RESAPP OVERSEAS R&D; EXPECTS $820k**

*** CANN GROUP TESTS GELPELL EQUIPMENT; HARVEST ONE PAYMENT**

*** MGC: UK APPROVES IMPORT, USE OF CANNEPIL+ FOR EPILEPSY**

*** TOTAL BRAIN: $600k ARR AS IBM SIGNS US VETERANS AFFAIRS**

*** RHYTHM FILES COLOSTAT MANUFACTURER FILE TO TGA**

*** OPTHEA 1.6m CEO RIGHTS, 4m DIRECTOR OPTIONS AGM**

*** SG HISCOCK TAKES 5% OF ATOMO**

*** JENCAY REDUCES TO 9.6% OF UNIVERSAL BIOSENSORS**

*** REGAL REDUCES TO 8.8% OF ADHERIUM**

*** SHIMANO, EX-M-D PETER GRIFFITHS BELOW 5% OF NEUROTECH**

*** ONE FUNDS, SAVILLE TAKE 5% OF IMRICOR**

*** LUMOS APPOINTS TRUMP S-G DR JEROME ADAMS ADVISER**

MARKET REPORT

The Australian stock market climbed 0.16 percent on Tuesday September 14, 2021, with the ASX200 up 12.1 points to 7,437.3 points. Sixteen of the Biotech Daily Top 40 stocks were up, 14 fell and 10 traded unchanged. All three Big Caps fell.

Prescient was the best on the exercise of 520,000 options, up 5.5 cents or 25.6 percent to 27 cents, with seven million shares traded. Optiscan climbed 8.7 percent; Uscom was up 7.4 percent; Genetic Signatures and Orthocell were up more than five percent; Medical Developments and Telix improved more than four percent; Alterity was up 3.3 percent; Actinogen, Kazia and Mesoblast rose more than two percent; Clinuvel and Next Science were up more than one percent; with Nanosonics, Starpharma and Volpara up by less than one percent.

Osprey led the falls, down 0.1 cents or 8.3 percent to 1.1 cents, with 780,480 shares traded. Impedimed fell four percent; Cynata and Pro Medicus lost more than three percent; Antisense, Immutep, Oncosil and Resmed shed more than two percent; Avita, Dimerix, Imugene and Paradigm were down more than one percent; with Cochlear, CSL, Cyclopharm, Opthea and Polynovo down by less than one percent.

MICRO-X

Micro-X says its Rover mobile x-ray has been included on the Australian Register of Therapeutic Goods and all variants can be sold commercially in Australia.
Micro-X said that the Rover already had US Food and Drug Administration clearance and was being sold globally where the 510(k) approval was recognized.
The company said it was the second product to receive TGA clearance, following the Carestream DRX Revolution Nano, which was listed on the Register in 2019.
Micro-X said that unlike the Nano, the Rover was Micro-X branded and would provide the higher revenue and margins that come with direct control of sales.
The company said that the Australian market for mobile x-ray equipment was estimated to be $10 million a year, with “a growing need and adoption of point-of-care x-ray imaging”.
Micro-X said the Rover’s “high-imaging performance and lightweight, rugged maneuverability” allowed door-to-door imaging services to be provided offering radiology exams in patients’ homes or in aged care facilities where patient mobility or potential infection control issues militate against fixed radiology sites.
Micro-X managing-director Peter Rowland said it was “fantastic now that we can really attack our own domestic market here in Australia with our own, highly price competitive, Australian made, proprietary product”.
“We’ve experienced a lot of local interest in our products now that Micro-X has become more well-known following our success overseas and, in these difficult times for healthcare providers, the importance of buying local is more widely embraced,” Mr Rowland said.
“We believe we can build a substantial market share here quite quickly and we’re keen to innovate as well, supporting new door-to-door home radiology services and bringing affordable, reliable, high-quality digital imaging to remote and rural medical facilities,” Mr Rowland said.
“We’re very excited by these opportunities ahead of us in Australia and New Zealand,” Mr Rowland said.
Micro-X was up one cent or 3.5 percent to 29.5 cents with 1.1 million shares traded.

TELIX PHARMACEUTICALS

Telix says the US Food and Drug Administration has accepted the investigational new drug application for a 29-patient, phase II trial of TLX250 as a kidney cancer therapy.
Telix said the 'Starlite 2' study was a single arm, investigator-led trial in patients with advanced clear cell renal cell carcinoma, the most common and aggressive kidney cancer, with TLX250 targeting carbonic anhydrase-IX (CA9), a protein highly expressed in patients likely to demonstrate a more limited response to cancer immunotherapy.
The company said the trial would evaluate TLX250-delivered radiation as an immune system primer, in combination with the anti-programmed death 1 (PD-1) immunotherapy nivolumab, marketed as Opdivo, with the primary endpoint the efficacy of combining immunotherapy with TLX250 as assessed by the number of tumors responding to the Telix therapy versus the standard-of-care alone.
Telix said the study's principal investigator would be the New York Sloan Kettering Cancer Centre's Dr Darren Feldman, who said that each year 76,000 Americans would be diagnosed with kidney cancer.
"The selective targeting of TLX250 to CA9 delivers radiation therapy directly to [clear cell renal cell carcinoma] tumors," Dr Feldman said.
"Combining this innovative approach with anti-PD-1/PD-L1 therapy could enhance existing immune-based treatments," Dr Feldman said.
Telix chief medical officer Dr Colin Hayward said the use of immunotherapies had "improved the outlook for patients with advanced clear cell renal cancer, but most patients eventually progress".
"This therapy, along with patient selection and treatment response assessment with our CA9-targeting imaging agent TLX250-CDx may potentially offer a new paradigm of more accurate staging and personalized treatment for kidney cancer patients," Dr Hayward said.
Telix was up 30 cents or 4.6 percent to $6.87 with two million shares traded.

TELIX PHARMACEUTICALS

Telix says it welcomes updated US National Comprehensive Cancer Network prostate cancer guidelines, which include 68-gallium-PSMA-11.
Telix said the guidelines cover prostate specific membrane antigen (PSMA) positron emission tomography (PET) imaging modalities, including 68Ga-PSMA-11.
The company said its Illuccix kit for the preparation of 68Ga-PSMA-11 injection new drug application was in the late stages of review by the US Food and Drug Administration.
Telix said that Cancer Network guidelines were a recognized standard for clinical direction and policy in cancer care and were used widely by clinicians and payors.
The company said that the Network panel recognized the increased sensitivity and specificity of PSMA-PET tracers, compared to conventional computed tomography (CT) and magnetic resonance imaging (MRI) imaging for detecting micro-metastatic disease, at both initial staging and biochemical recurrence.
Telix said the guidelines stated that the panel "does not feel that conventional imaging is a necessary prerequisite to PSMA-PET and that PSMA-PET/CT or PSMA-PET/MRI can serve as equally effective, if not more effective front-line imaging tools for these patients".
"The updated guidelines now include Ga-68-PSMA-11 PET/CT to be considered as an alternative to standard imaging of bone and soft tissue," the company said.
Telix chief medical officer Dr Colin Hayward said the change was important and would "influence a shift in clinical practice to consider PSMA-PET imaging as an alternative to standard imaging of bone and soft tissue for the detection of unfavorable intermediate, high and very high risk as well as recurrent prostate cancer".

CRONOS AUSTRALIA

Cronos says it will acquire medical marijuana company CDA Health Pty Ltd, for up to 439,784,282 shares subject to conditions including shareholder approvals.

Cronos said the merger agreement with the Varsity Lakes, Gold Coast, Queensland-based CDA (formerly Cannabis Doctors Australia) provided for cash payments of up to $5 million in cash for CDA shares subject to certain conditions precedent.

The company said CDA's more than 500 shareholders would be offered 21.534 Cronos shares for every CDA share, with the number of shares to be determined by the extent that certain CDA shareholders take a portion in cash.

Cronos said the deemed value of consideration shares was 13.8 cents, valuing CDA at $60,690,231 and following completion, CDA shareholders would own between 75.3 percent of Cronos if no cash was taken and 73.7 percent if the full $5 million was taken.

The company said CDA was founded in 2018 by Guy Headley, Dr Ben Jansen, Jessimine Jansen and Dr Matua Jansen and generated more than $21 million in sales in 2020-'21, generating unaudited earnings (Ebitda) of $2,206,026.

Cronos said CDA had a national wholesale distribution of medical marijuana products and wholly-owned subsidiary Burleigh Heads Cannabis Pty Ltd operated a pharmacy and the Canview doctor online portal which distributes more than 120 different products in Australia from international and domestic producers, as well as operating clinics via its subsidiary Cannabis Doctors Australia Pty Ltd, and Cannabis Doctors Aotearoa which imports medical marijuana prescribed by New Zealand doctors.

The company said that CDA owned Healthy Not High Pty Ltd, a hemp food business.

Cronos said the merger would provide "a material increase in both size and scale of its operations and a route to early profitability for the integrated group".

The company said it would continue to benefit from its relationship with shareholder, Cronos Group Inc, whose chief executive officer Kurt Schmidt would join the combined entity's board, post-completion, with Shane Tanner continuing as Cronos Australia's independent chair, Rodney Cocks remaining as executive director and chief executive officer and Thomas Howitt continuing as chief financial officer and company secretary.

Cronos said CDA was entitled to three directors and had nominated Guy Headley, Dr Ben Jansen and Dr Marcia Walker for election at a November extraordinary general meeting, with current directors Michael Gorenstein, Jason Adler, Daniel Abrahams and Anna Burke resigning from the Cronos board on completion.

"The merger with CDA Health is another key milestone achieved by Cronos Australia since its [initial public offer] in late 2019," Mr Tanner said. "This transaction should propel the integrated business to a position of market leadership in Australia and position it for sustainable, profitable growth."

Cronos said it had reviewed its option on a leasehold site in Smeaton, Victoria for a cultivation and manufacturing facility, and would not exercise its rights with Glenbrook Pastoral Pty Ltd, which lapse on June 30, 2022.

The company said it had in-principle ASX advice that it would not require shareholder approval under Listing Rule 11.1.2 and will not be required to re-comply with Chapters 1 and 2 of the ASX Listing Rules, but certain CDA shareholders would acquire voting power of more than 20 percent, so an independent expert would provide an opinion on whether the merger was fair and reasonable to Cronos shareholders.

The company said it and CDA would hold investor meetings in November with completion expected on November 29, 2021.

Cronos provided a table showing the merged group with assets of $21,395,837, revenue of $23,417,081 and a projected loss of $1,721,467.

Cronos was up 2.5 cents or 23.8 percent to 13 cents with one million shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says Melbourne's Peter MacCallum Cancer Centre will supply patient samples to develop and validate its Tn Antigen point-of-care cancer biosensor.
Universal Biosensors said the agreement with the Cancer Centre would provide access to plasma samples collected from patients with colorectal, breast and prostate cancer.
Universal Biosensors chief executive officer John Sharman told Biotech Daily that "the Tn antigen is produced by many different cancer types, but rarely by healthy cells".
The company said the trial was expected to begin in October with results by April 2022, which would be used to confirm the presence of Tn in multiple cancer types and determine the clinically relevant range of Tn concentrations.
Universal Biosensors said its objective was for the handheld Tn biosensor to accurately measure a patient's cancer status by monitoring remission and reoccurrence in easier, cheaper and more frequent tests.
Mr Sharman said the trial results and any subsequent development work would form part of a Tn regulatory approval application.
"Potentially the Tn biosensor may be used for early cancer diagnosis, disease staging and monitoring of treatment effectiveness," Mr Sharman said.
Universal Biosensors was unchanged at 90 cents.

VGI HEALTH TECHNOLOGY (FORMERLY AZURE HEALTH TECHNOLOGY, MERGED WITH INVICTUS BIOPHARMA)

VGI says the Brisbane-based Gallipoli Medical Research Foundation will conduct an 80-patient phase II trial of IVB001 for non-alcoholic fatty liver disease/steatohepatitis.
VGI said that the randomized, double-blind, placebo-controlled trial would be conducted through subsidiary Invictus Ops Pty Ltd, with seven of eight sites recruited.
Last year, the then Azure said it was preparing for the trial of IVB001 for nonalcoholic fatty liver disease and non-alcoholic steatohepatitis (BD: Jun 15, 2020)
Today, Gallipoli research director Prof Darrell Crawford said that nonalcoholic fatty liver disease (NAFLD) and non-alcoholic steato-hepatitis (NASH) was "a difficult and intractable disease to treat and there are currently no treatments approved by major regulatory bodies such as the Therapeutic Goods Administration here in Australia or the Food and Drug Administration in the US".
"IVB001 has the potential to address several aspects of this challenging disease including the steatosis, [or] gathering of fat in liver cells, the inflammation caused by the steatosis and the fibrosis, [or] scarring caused by collagen," Prof Crawford said.
VGI said the study would analyze the efficacy and safety of IVB001, a compound based on the non-invasive, direct delivery of tocotrienols using its transmucosal delivery platform.
The company said Datapharm Australia Pty Ltd was expecting to submit an ethics application study in the next few weeks, with a final data readout expected by April 2023.
On the National (formerly Newcastle) Stock Exchange, VGI was untraded at 15 cents.

RESAPP HEALTH

Resapp says the Federal Department of Industry, Science, Energy and Resources has approved its off-shore claims for the Research and Development Tax incentive.
Resapp said the advanced overseas finding related to the years to June 30, 2021, 2022 and 2023, and it expected to receive an additional tax incentive of $820,000 for the year to June 30, 2021.
Resapp fell 0.7 cents or 7.9 percent to 8.2 cents with 36.0 million shares traded.

CANN GROUP

Cann Group says Gelpell capsule manufacturing equipment is being commissioned at its Mildura marijuana facility, and it will issue 2,725,863 shares to Harvest One Cannabis Inc.
Cann Group said the equipment was shipped from Switzerland and arrived on-site at Mildura growing and extraction facility for inspection late last month.
The company said the delivery and installation of the Gelpell manufacturing line, together with other equipment and commissioning activity was “a key milestone in the ramp-up to production at Cann’s new $117 million state-of-the-art cultivation and manufacturing facility and a subsequent step-change in the economics of the business”.
Cann Group said that acceptance of the Gelpell production equipment triggered the payment included in the February Satipharm acquisition (BD: Feb 15; Mar 11, 2021).
The company said that the 2,725,863 shares were issued to the Vancouver, British Columbia-based Harvest One at 29.5 cents each, equivalent to $C750,000 ($A804,000), with the share price calculated as the 30-day volume-weighted average price to September 7, 2021.
Cann said validation and verification batches of Gelpell capsules would be produced to meet clinical good manufacturing practice inspection requirements and for stability testing.
Cann Group said it would continue to have Satipharm cannabidiol (CBD) products manufactured in Switzerland to meet European requirements, and formulation activity at Mildura would focus on the production of a combined tetrahydrocannabinol (THC) and CBD product for medicinal purposes and a low dose CBD only product in anticipation of Australian registration approval for an over-the-counter pharmacist S3 capsules.
The company said that the investment in the Gelpell manufacturing technology and equipment was expected to deliver cost savings of about 60 percent, compared to contract manufacturing costs.
Cann chief executive officer Peter Crock said the works at Mildura were “key milestones in the ramp-up of production activity … and have been achieved despite ongoing challenges associated with Covid-19 delays relating to delivery of equipment, on-site restrictions and the availability of specialist contractors”.
“The new Mildura facility aims to deliver scale benefits, substantial cost savings and improved supply chain security and we anticipate will provide the platform for strong profitable growth of the business,” Mr Crock said.
“We are continuing to monitor and manage the impacts relating to Covid and will provide regular updates on progress at Mildura as we continue to track towards full commissioning of both manufacturing and cultivation activity,” Mr Crock said.
Cann Group fell half a cent or 1.75 percent to 28 cents with 2.7 million shares traded.

MGC PHARMA

MGC says its Cannepil+ for drug-resistant epilepsy has been approved for import by the UK Medicine and Healthcare products Regulatory Agency.
MGC said that Cannepil+ was a biosimilar effect-identical product of its Cannepil phyto-cannabinoid and Cannepil+ was approved for prescription for patients in the UK.
MGC said it was “the first time that an epilepsy treatment currently in a clinical trial process, and containing [tetrahydrocannabinol], has been approved by the authorities in the UK for import”.
The company said Cannepil+ would be made available for free on compassionate grounds to 10 patients for six months, with treatment monitored as part of an observational trial using a data collection software application, provided by London’s Alta Flora.
MGC was up 0.7 cents or 11.7 percent to 6.7 cents with 19.3 million shares traded.

TOTAL BRAIN

Total Brain says its partner IBM has a contract with the first US government client of the IBM Health & Wellness 360 platform.
Total Brain said that it supplied its platform for use within IBM's software application, and the roll-out of IBM's application was for 25,000 US Veterans Affairs users, which would be $600,000 in annual recurring revenue.
The company said that the contract had provisions for potential deployment to hundreds of thousands of users over the next two years, and IBM's platform was being introduced as a health and resources tool and was funded directly from the Government agency's budget.
Total Brain said the announcement was "an important milestone" for its brain health platform.
Total Brain was up half a cent or 1.85 percent to 27.5 cents.

RHYTHM BIOSCIENCES

Rhythm says the Australian Therapeutic Goods Administration has accepted its manufacturers evidence documentation, required for Colostat approval.
Rhythm said the TGA submission process for the Colostat blood test for the early detection of colorectal cancer completed the first step for Australian regulatory approval.
The company said the next step would be filing for an Australian Register of Therapeutic Goods listing, which required "comprehensive documentation such as the product technical files [and] clinical evaluation reports".
Rhythm chief executive officer Glenn Gilbert said that Conformité Européenne (CE) mark approval was a separate process and was "on track for late this calendar year".
Rhythm was up seven cents or 6.7 percent to $1.12.

OPTHEA

Opthea will vote to grant 1,600,000 performance rights to chief executive officer Dr Megan Baldwin, with 4,000,000 options for directors Dr Julia Haller and Judith Robertson.
Opthea said the annual general meeting would vote to issue Dr Baldwin the performance rights, vesting on continuity of service, specified OPT-302 trial milestones including completion of recruitment, results read-outs and US Food and Drug Administration approval of OPT-302.
The company said it proposed to issue 2,000,000 options each to Dr Haller and Ms Robertson, exercisable at the 5-day volume-weighted average price to the grant date, vesting over three years and exercisable within four years.
The company's notice of meeting said shareholders would vote on the remuneration report, the long-term incentive plan and the election of directors Michael Sistenich, Lawrence Gozlan, Dr Haller and Ms Robertson.
The meeting will be held on-line on October 19, 2021 at 9am (AEDT).
Opthea fell half a cent or 0.4 percent to $1.355.

ATOMO DIAGNOSTICS

The Sydney-based SG Hiscock and Co says it has become substantial holders in Atomo with 20,909,532 shares or 5.12 percent.
SG Hiscock said the shares were acquired between July 1 and September 7, 2021 with the single largest acquisition 650,000 shares for $152,750 or 23.5 cents a share.
Atomo was unchanged at 28.5 cents with 2.3 million shares traded.

UNIVERSAL BIOSENSORS

Jencay Capital says it has reduced its substantial shareholding in Universal Biosensors from 18,817,214 shares (10.59%) to 17,024,745 shares (9.58%).
The Sydney based Jencay Capital said that between June 16 and September 10, 2021 it sold 1,792,469 shares for $1,508,433 or 84.15 cents a share.

ADHERIUM

Regal Funds Management says it has reduced its substantial shareholding in Adherium from 222,266,463 shares (10.46%) to 187,196,934 shares (8.79%).
The Sydney-based Regal Funds said that on September 9, 2021 it sold 35,069,529 shares for $895,966 or 2.555 cents a share.
In May, Regal said it bought 169,548,136 shares at 1.5 cents a share (BD: May 12, 2021).
Adherium was up 0.1 cents or 5.3 percent to 1.8 cents with 54.2 million shares traded.

NEUROTECH INTERNATIONAL

Shimano Ventures and former Neurotech managing-director Peter Griffiths say they have been diluted below the five percent substantial level in the company.
Last year, the Vaduz, Liechtenstein-based Shimano and Mr Griffiths said they held 24,249,984 shares or 6.24 percent of the company (BD: Oct 5, 2020).
Two weeks later, Neurotech said it had appointed Brian Leedman chair, director Dr David Cantor retired and Mr Griffith had been appointed head of subsidiary AAT Research.
Today, Shimano and Mr Griffiths said they were diluted on November 12, 2020 following the $2.5 million placement at 2.2 cents a share (BD: Nov 2, 2020).
Neurotech was up 0.2 cents or 4.55 percent to 4.6 cents.

IMRICOR MEDICAL SYSTEMS

Sydney's One Funds Management and Saville Capital Emerging Companies Fund say they have become substantial holders in Imricor with 7,180,000 shares (5.05%).
One Funds and Saville said that they bought and sold shares between September 4, 2020 and September 10, 2021 with the largest acquisition 1,500,000 shares for $1,500,000.
Imricor fell six cents or five percent to $1.13.

LUMOS DIAGNOSTICS

Lumos says it has appointed Dr Jerome Adams as a "strategic healthcare adviser".
Lumos said that Dr Adams was the twentieth Surgeon-General of the United States of America from 2017 to 2021.
It was widely reported that Dr Adams resigned at the request of President Joe Biden.
The company said that Dr Adams had "a real-world public health perspective to the ongoing impact of global issues such as antimicrobial resistance and Covid-19".
Lumos said that Dr Adams would advise on its point-of-care diagnostics, beginning with the launch of the Febridx blood test to differentiate between bacterial and viral infections.
Lumos fell three cents or 2.6 percent to $1.115.