Biotech Daily

Tuesday March 19, 2024

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: UNIVERSAL BIO UP 53%; POLYNOVO DOWN 7%**

*** CYCLOPHARM IMAGES 1st US CLINICAL TECHNEGAS PATIENTS**

*** ISLAND RIGHTS OFFER RAISES $1.95m**

*** MONASH, MIPS, BAKER TARGET ANXA1 FOR HEART DISEASE, IN MICE**

*** TELIX PARTNERS WITH ABX-CRO FOR QDOSE SOFTWARE**

*** UNIVERSAL BIOSENSORS WINS XPRECIA FDA 510(k), CLIA APPROVAL**

*** LTR DOSES 1st SPONTAN E-D PATIENT**

*** INOVIQ 'EXOSOMES FOR PREGNANCY COMPLICATIONS'**

*** MGC PHARMA EGM 99.7% BACK 'ARGENT BIOPHARMA' NAME CHANGE**

*** RESPIRI 167m INVESTOR, 60m DIRECTOR OPTIONS EGM**

*** AUSTRALIAN ETHICAL INCREASES, DILUTED TO 17.5% OF NOVA EYE**

*** JENCAY BELOW 5% OF NOVA EYE**

*** SIEMENS BELOW 5% OF IMRICOR**

*** RHYTHM APPOINTS DR BENTON, PROF EMERY, PROF MACRAE ADVISERS**

MARKET REPORT

The Australian stock market was up 0.36 percent on Tuesday March 19, 2024, with the ASX200 up 27.4 points to 7,703.2 points. Twelve of the Biotech Daily Top 40 stocks were up, 21 fell and seven traded unchanged.

Universal Biosensors was the best, up 8.5 cents or 53.1 percent to 24.5 cents with 33.9 million shares traded. Proteomics climbed 16.4 percent; Curvebeam was up 8.3 percent; Atomo rose 7.4 percent; Paradigm was up 4.05 percent; Actinogen rose 3.2 percent; Alcidion, Immutep and Impedimed improved two percent or more; Dimerix, Emvision and Resmed were up one percent or more; with Neuren up 0.05 percent.

Polynovo led the falls, down 16 cents or 6.8 percent to $2.19, with 3.0 million shares traded. Compumedics lost 6.1 percent; Cynata was down 5.6 percent; 4D Medical, Avita and Micro-X fell more than four percent; Nanosonics was down 3.3 percent; Clarity, Pro Medicus and Telix shed more than two percent; Clinuvel, Cyclopharm, Mesoblast, Next Science, Opthea, Orthocell, Percheron (Antisense), Prescient and SDI were down more than one percent; with Cochlear, CSL, Genetic Signatures and Medical Developments down by less than one percent.

CYCLOPHARM

Cyclopharm says the first clinical patients have been imaged with its Technegas radio-pharmaceutical device for lung ventilation in the US.

Cyclopharm said the milestone was conducted in patients last week at two clinical sites in St Louis, Missouri and Stanford, California.

The company said the “landmark events” followed its US Food and Drug Administration approval of Technegas and the commercialization of the product at US medical facilities, and it was continuing efforts to convert clinical demand to contract signoff.

Last year, Cyclopharm said that the FDA had approved the Technegas system for pulmonary embolism imaging (BD: Oct 2, 2023)

Cyclopharm said imaging the first clinical patients in the US signified “immediate and ongoing clinical revenues for Technegas”.

Last year, Cyclopharm managing-director James McBrayer told Biotech Daily that the company would receive $US7,000 ($A10,585) for the installation of the Technegas generator and a licence fee of $US7,000 a year, as well as a per patient payment of $US225 (BD: Dec 5, 2023).

Today, Mr McBrayer said the company was “very pleased to see the clinical use of Technegas underway within days of installation and training at these sites and look forward to implementing Technegas to their affiliate locations in the coming months”.

“Most significant is the fact that US patients are now benefitting from our Technegas technology, joining those in 64 other countries globally where our leading imaging solution is already established,” Mr McBrayer said.

“We are grateful for the ongoing clinical guidance and partnership of the clinical leaders at these locations as well as for the support of the entire nuclear medicine and administration teams who have helped us navigate through the implementation process,” Mr McBrayer said. “We are very pleased that these sites are the first to use Technegas clinically in the US.”

Cyclopharm fell two cents or 1.1 percent to $1.78.

ISLAND PHARMACEUTICALS

Island says it has raised $1.95 million in its two-for-five, non-renounceable rights offer at 6.0 cents a share.

Last month, Island said it expected to raise about $1.95 million through the fully underwritten rights offer (BD: Feb 26, 2024).

At that time, the company said investors would receive one attaching option exercisable at six cents each within 12 months from the rights offer closing date, and an additional option for each option that was exercised within three months of the closing date.

Today, Island said that shareholders had taken up about 8.92 million shares, or about 27.4 percent of the shares on offer, with the remaining about 23.58 million shortfall shares to be taken up by underwriter PAC Partners Securities Pty Ltd.

The company said the funds would be used to analyze its phase I dose and prepare for the phase II trial of ISLA-101 for dengue fever and other mosquito borne viruses.

Island said if the attaching options and piggy-back options were exercised, it would use the funds to advance its phase II efficacy study.

Island managing-director Dr David Foster said the company was “very pleased to have had strong support for this offer, enabling it to be fully-underwritten”.

“With this new capital, we are well financed to progress our immediate clinical goals for our lead asset, ISLA-101,” Dr Foster said.

Island was unchanged at six cents with 48.6 million shares traded.

MONASH UNIVERSITY, BAKER HEART AND DIABETES INSTITUTE
MONASH INSTITUTE OF PHARMACEUTICAL SCIENCES

Monash University says researchers have shown the ANXA1 protein could slow the progression of age-related cardio-vascular diseases and regulate blood pressure, in mice.
Monash University said researchers from the Monash Institute of Pharmaceutical Sciences and the Baker Heart and Diabetes Institute studied the naturally occurring protein annexin A1, or ANXA1, and found it could "potentially shield against the detrimental effects of ageing on blood pressure and cardio-vascular health".
Monash University said the study supported "the development of a new class of drugs to regulate blood pressure and age-associated changes in cardio-vascular function".
Monash said the study, titled 'The pro-resolving mediator, annexin A1 regulates blood pressure, and age-associated changes in cardiovascular function and remodeling' was published in the Federation of American Societies of Experimental Biology and available at: https://faseb.onlinelibrary.wiley.com/doi/10.1096/fj.202301802R.2.
Monash Institute of Pharmaceutical Sciences laboratory head and study lead author Dr Chengxue Helena Qin said the role of ANXA1 in slowing down the progression of age-related cardio-vascular diseases had previously not been widely explored.
"In mice, our pre-clinical studies concluded that ANXA1 could play a critical role in controlling blood pressure, how well your heart works, and even stopping heart problems from getting worse," said Dr Qin.
"Middle-aged mice lacking ANXA1 experienced more inflammation and damage in their hearts and blood vessels," Dr Qin said. "This indicates that untreated inflammation might play a role in causing heart and blood vessel problems as we age."
"Consequently, it could open up new possibilities for treating high blood pressure and preventing heart issues linked to ageing," Dr Qin said.

TELIX PHARMACEUTICALS

Telix says it will use the Dresden, Germany-based ABX-CRO's Qdose dosimetry analysis software platform for its radio-pharmaceutical therapies and diagnostics.
In an email to investors not released to the ASX, Telix said the ABX-CRO Advanced Pharmaceutical Forschungsgessellschaft mbH's Qdose was validated software developed with Stockholm's Quantinm AB, had US Food and Drug Administration 510(k) clearance and EU Conformité Européenne mark, and was used to estimate patient-specific dosimetry for both therapeutic and diagnostic radio-pharmaceuticals.
Telix managing-director Dr Chris Behrenbruch said that nuclear medicine used dosimetry analysis to calculate the absorbed dose of radiation in different parts of the body.
The company said it would use the Qdose to optimize treatment responses while reducing effects on normal healthy organs and the more efficient use of isotope supply chains.
Telix said Qdose supported "dosimetry calculations using planar imaging, tomographic imaging, single and, or multi-time point imaging and hybrid combinations [with] … additional tools for attenuation and background correction".
Telix said Qdose would be integrated into its products as an accessible tool for clinicians and third-party commercial drug developers.
Dr Behrenbruch said "rapid, reliable and personalized dosimetry is becoming an increasingly important future direction of cancer care and regulatory authorities now expect to see dosimetry analysis".
"Qdose has an excellent performance track record, and we are committed to positioning Qdose as a new industry standard in dosimetry analysis," Dr Behrenbruch said.
Telix fell 35 cents or 2.8 percent to $12.15 with 1.3 million shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says it has US Food and Drug Administration 510(k) and CLIA approval to sell its Xprecia prime blood coagulation analyser in the US.

Universal Biosensors said the Xprecia Prime portable device was designed to measure prothrombin time and international normalized ratio (PT/INR) to monitor the dosage of vitamin K antagonists in patients taking anti-clotting medication.

The company said the FDA 510(k) clearance and Clinical Laboratory Improvement Amendments (CLIA) allowed it to sell Xprecia Prime to healthcare professionals, including CLIA waived facilities, such as hospitals, clinics and doctor's offices.

Universal Biosensors said the approval was for the use of Xprecia Prime to measure the full range of 0.8 to 8.0 international normalized ratio.

Universal Biosensors managing-director John Sharman said approval to sell Xprecia Prime in the US was "a historic moment [and] … represents more than 10 years of research and development work and many millions of dollars of investment."

"This is the first time the FDA have granted a CLIA waiver by application to any coagulation device, and it is testament to the performance of Xprecia Prime," Mr Sharman said.

"The number of PT/INR tests performed in clinics is the largest part of the US market so to have won unrestricted access to all clinics and hospitals across the US is a major achievement," Mr Sharman said.

"This FDA approval represents the first opportunity in Universal Biosensor's history to access the lucrative, and fully reimbursed, US market," Mr Sharman said.

"Our expectation is Xprecia Prime will qualify under the existing reimbursement codes used by Medicare, Medicaid and US Health insurers," Mr Sharman said.

"Universal Biosensors has a pipeline of sales and distribution contracts already in negotiation and now that we have FDA approval, we expect to conclude some, if not all of these contracts, win market share and generate substantial revenue for the company," Mr Sharman said.

Universal Biosensors was up 8.5 cents or 53.1 percent to 24.5 cents with 33.9 million shares traded.

LTR PHARMA

LTR says it has dosed the first of 18 patients in its bio-equivalence study of 5mg Spontan nasal spray compared to 10mg vardenafil (Levitra) tablet for erectile dysfunction.

LTR said the single-dose, randomized, four-week study would evaluate the bioavailability of 5mg of the phosphodiesterase-5, or PDE5, inhibitor vardenafil administered as a nasal spray, called Spontan, compared to the standard 10mg Vardenafil oral tablets.

The company said the study was specifically designed to meet US Food and Drug Administration requirements and other regulatory requirements, with results expected in "mid-2024".

LTR chair Lee Rodne said the study was "off to a great start, and we are grateful to the participants interested in entering the study".

"Spontan nasal spray represents a potential paradigm shift in the treatment for erectile dysfunction and is a promising disruptor to the global blockbuster PDE5 market, offering a discreet and efficient treatment alternative," Mr Rodne said.

"We are excited to bring this key innovation to men worldwide," Mr Rodne said.

LTR fell half a cent or 1.6 percent to 30 cents.

INOVIQ

Inoviq says a research paper shows extracellular vesicles, including exosomes, can be used “for non-invasive prenatal testing to manage pregnancy complications”.
Inoviq said the paper highlighted the need for specific and scalable exosome isolation methods, such as its Exo-net and Exo-ace exosome isolation technologies.
The company said the paper titled ‘IFPA Joan Hunt senior award in placentology lecture: Extracellular vesicle signalling and pregnancy’ was co-authored by its chief scientific officer Prof Gregory Rice and published online in the journal Placenta, with the full article available at https://pubmed.ncbi.nlm.nih.gov/38458919/.
Inoviq chief executive officer Dr Leearne Hinch said “developing accurate and reliable [extracellular vesicles]-based diagnostics requires identification of disease-associated biomarkers and specific and scalable exosome isolation methods”.
“Use of exosomes for non-invasive pre-natal testing to manage pregnancy complications is an exciting possibility and now within reach,” Dr Hinch said.
“Inoviq has solved this key industry challenge with its proprietary Exo-net and Exo-ace technologies that enable fast, efficient and scalable exosome isolation for commercial applications in diagnostics and therapeutics,” Dr Hinch said.
Inoviq was up 2.5 cents or 4.4 percent to 59 cents.

MGC PHARMACEUTICALS

MGC says its extraordinary general meeting passed all resolutions with 99.67 percent in favor of changing its name to ‘Argent Biopharma’.
In 2016, MGC told Biotech Daily that it had completed a backdoor listing into Perth gold-mining company Erin Resources to sell its cannabinoid compounds (BD: Mar 4, 2016).
Last month, the company said ‘Argent Biopharma’ “more accurately reflects the future … of the company” and if passed, it would trade under the code ‘RGT’ (BD: Feb 13, 2024).
Today, MGC said all other resolutions including the issue of incentive options to directors, and the ratification of placement and creditor shares passed by more than 95.98 percent.
Last year, the company said 96.6 percent of an extraordinary general meeting voted in favor of a 1,000-to-one consolidation (BD: Oct 26, 2023).
MGC fell one cent or 2.4 percent to 41 cents with 43 (forty-three) shares traded.

RESPIRI

Respiri says investors will vote to issue 166,666,667 shares to Benjamin Richards and 60,000,000 options to chair Nicholas Smedley and managing-director Marjan Mikel.
Last year, Respiri said it raised $6.5 million in a placement at 3.0 cents a share, and a $20 million commitment facility from Principal Wealth Group (BD: Dec 14, 2023).
At that time, Respiri said cornerstone investor and Principal Wealth Group director Mr Richards was lead manager and had taken up about $5 million in the placement.
Today, the company said its extraordinary general meeting would vote to issue 30,000,000 options each to Mr Smedley and Mr Mikel following a failure to issue the unlisted options within one month of the annual general meeting, which last year voted more than 94.2 percent to issue the options (BD: Oct 13, 2023).
Today, the company said its former company secretary “did not issue the options within one month of shareholder approval being obtained” and it was seeking re-approval.
The meeting will be held online on April 18, 2024 at 10am (AEST).
Respiri was up 0.1 cents or 3.45 percent to three cents with 1.7 million shares traded.

NOVA EYE MEDICAL

Australian Ethical Investment says it has increased its substantial holding in Nova Eye and been diluted from 27,585,007 shares (19.20%) to 40,113,310 shares (17.53%).
Australian Ethical said that between March 6, 2023 and February 14, 2024 it bought and sold shares, with the single largest purchase 2,975,401 shares for $624,834, or 21.0 cents a share, and was diluted due to the issue of 15,884,750 shares on March 15, 2024.
Last month, Nova Eye said it had raised $10.9 million in a placement and rights offer at 21 cents a share (BD: Feb 12, 14; March 15, 2024).
Nova Eye was unchanged at 20.5 cents.

NOVA EYE MEDICAL

Sydney's Jencay Capital Pty Ltd says it has reduced and been diluted below the five percent substantial shareholder level in Nova Eye.
Jencay said that between May 5, 2023 and March 15, 2024 it sold 2,286,854 shares for $484,165 or 21.2 cents a share and was diluted in the recent capital raise (see above).
Biotech Daily calculates that Jencay retains 11,001,102 Nova Eye shares or 4.8 percent.

IMRICOR MEDICAL SYSTEMS

Imricor says Siemens Medical Solutions USA has ceased to be a substantial shareholder with its 8,384,150 Chess depository interests (CDIs) diluted to 4.46 percent.
Last month, Imricor said it had raised $8.639 million through placements and rights offers at 45.0 cents per CDI (BD: Feb 5, 27, 2024).
Imricor was untraded at 49.5 cents.

RHYTHM BIOSCIENCES

Rhythm says it has appointed Dr Sally Benton, Prof Jon Emery and Prof Finlay Macrae as clinical advisers to oversee the development of its Colostat test for colorectal cancer.
Rhythm said Dr Benton was a consultant clinical biochemist and clinical lead at England's Berkshire and Surrey Pathology Services and director of bowel cancer screening at Guildford's Royal Surrey County Hospital.
The company said Prof Jon Emery was a professor of primary care cancer research at the University of Melbourne, primary care research and education lead at the Victorian Comprehensive Cancer Centre and a director of the Cancer Australia Primary Care Collaborative Cancer Clinical Trials Group.
Rhythm said Prof Macrae was head of colorectal medicine and genetics at the Royal Melbourne Hospital and was a lead clinician at the Familial Cancer Clinic.
Rhythm executive chair Otto Buttula said the company was "honored to have world-class, distinguished leaders in their field of colorectal cancer diagnostics form our [clinical advisory board] and look forward to their expertise and guidance in this significant commercialization stage of Colostat".
Rhythm was unchanged at 9.5 cents.