Biotech Daily

Monday February 6, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: NOVA EYE UP 17%; CYCLOPHARM DOWN 10.5%**

*** IMAGION TRIAL REVIEW BACKS MAGSENSE FOR ALL CANCER MRI**

*** CORRECTION: RESMED**

*** ANTERIS PROPOSES $50m DRAW-DOWN EQUITY FACILITY**

*** GENETIC TECHNOLOGIES ADSs TO RAISE $7.2m**

*** RESPIRI REIMBURSED IN US FOR WHEEZO RPM**

*** UNIVERSAL BIOSENSORS DELIVERS XPRECIA PRIME TO EUROPE**

*** IMMUTEP ENROLS IMP321 INSIGHT-003 NSCLC TRIAL**

*** WEHI WINS NHMRC $1.3m FOR RAPID MALARIA TEST**

*** CRONOS BECOMES VITURA; ASX CODE CHANGE TO VIT**

*** EMYRIA, WOKE WELCOME TGA MDMA, PSILOCYBIN DECISION**

MARKET REPORT

The Australian stock market fell 0.25 percent on Monday February 6, 2023, with the ASX200 down 19.1 points to 7,539.0 points. Eleven of the Biotech Daily Top 40 stocks were up, 19 fell, nine traded unchanged and one was untraded. All three Big Caps fell.

Nova Eye was the best, up four cents or 16.7 percent to 28 cents, with 50,380 shares traded. Kazia, Mesoblast and Universal Biosensors climbed more than eight percent; Cynata improved 7.9 percent; Next Science was up 5.6 percent; Avita was up 3.75 percent; Actinogen rose 2.1 percent; Impedimed and Pharmaxis were up more than one percent; with Emvision up by 0.9 percent.

Cyclopharm led the falls, down 16.5 cents or 10.5 percent to $1.40, with 20,001 shares traded.

Patrys lost 6.45 percent; Resonance retreated 5.2 percent; Neuren, Oncosil and Prescient fell more than four percent; Amplia, Immutep, Imugene, Micro-X and Paradigm were down three percent or more; Antisense, Nanosonics and Pro Medicus shed more than two percent; Medical Developments, Opthea and Telix were down more than one percent; with Clinuvel, Cochlear, CSL, Proteomics and Resmed down by less than one percent.

IMAGION BIOSYSTEMS

Imagion says it will prioritize development of its Magsense nanoparticle technology as imaging agents for mainstream clinical magnetic resonance imaging (MRI) scanners.

Imagion said that an independent, blinded review by a panel of expert breast cancer radiologists corroborated its previously reported findings that Magsense had the potential to detect tumor cells in lymph nodes by MRI.

The company said that each radiologist ascertained that the Magsense human epidermal growth factor receptor 2 (HER2) imaging agent "produced a change in image contrast and that the contrast in nodes highly suspicious for tumor was distinctly different from the magnetic resonance imaging (MRI) contrast seen in non-involved nodes".

The study's principal investigator Dr Jane Fox said that the review was very encouraging".

"The assessments by these experienced breast radiologists are in line with our thinking that these early patient results are showing that the Magsense HER2 imaging agent is adding valuable information that can be used to better assess a patient's medical condition before starting treatment or planning surgery," Dr Fox said.

Imagion said that the independent reviews were "consistent with the company's previous assertion that the Magsense imaging agent provides new information for the radiologist not available through conventional methods, like ultrasound, and has the potential to aid in the clinical assessment of nodal metastasis in HER2 positive breast cancer".

The company said the panel assessment has "significant implications" given that MRI was part of clinical workflows and clinical decision making with a large installed base of scanners and trained radiologists, which would "help drive faster clinical adoption".

Imagion said the findings and change of priorities would eliminate near-term expense and risks associated with developing and introducing a new type of detection technology and showed the clinical potential for a pipeline of imaging agents targeting other cancers.

Imagion executive chair Bob Proulx said the outcome of the independent review was "welcome news, indeed".

"We now have a clear indication that our Magsense magnetic nanoparticle technology could work with the existing medical imaging infrastructure to provide the clinical benefit to breast cancer patients we have been aiming for," Mr Proulx said. "This takes a lot of the technical risk out of the future and will significantly facilitate market entry by eliminating the need to design, make, sell, and support new machinery."

"We will continue to refine our proprietary relaxometry technology but can now confidently shift our resources to developing our nanoparticles for use with MRI, a ubiquitous imaging modality used in hospitals and radiology clinics throughout the world," Mr Proulx said.

"We believe this will be more attractive for strategic partners and more likely for us to achieve commercial success sooner," Mr Proulx said.

"Since all Magsense targeted imaging agents use the same underlying magnetic nanoparticle technology, the company plans to prioritize the development of its Magsense nanoparticle technology for use with mainstream clinical MRI scanners," Mr Proulx said.

Imagion said that it had begun the regulatory process with the US Food and Drug Administration to bring the HER2 breast cancer clinical studies to the US where there would be access to a larger number of sites and a more substantial patient population.

The company said that the FDA had designated Magsense as a medical device, but recent US legislation stipulated that any MRI contrast agent be regulated as drugs through the imaging group within the Center for Drug Evaluation and Research.

Imagion said it did not expect the change to seek approval for its imaging agents for use with commercially available MRI scanners to significantly impact the time or cost associated with obtaining regulatory approvals.

Imagion was up 0.4 cents or 18.2 percent to 2.6 cents with 55.75 million shares traded.

CORRECTION: RESMED

Friday's edition incorrectly said that Resmed would continue to "increase revenue at a compound annual rate of 17 to 18 percent".
While Biotech Daily certainly hopes this may be the case, the company said it would "increase volume at a compound annual rate of 17 to 18 percent" – which is different.
The Friday sub-editor has been summarily dismissed and Biotech Daily apologizes without reservation to Resmed for the inaccuracy, while hoping the accidental premonition comes true.
Resmed fell 28 cents or 0.9 percent to $32.03 with 15.1 million shares traded.

ANTERIS TECHNOLOGIES

Anteris says it expects to have a $50 million standby equity purchase agreement with the Mountainside, New Jersey-based Yorkville Advisors Global by the end of February, 2023.
Anteris said that, subject to due diligence and internal approvals, it could issue a drawdown notice of up to $50 million over 36-months with shares to be issued at 93 percent of the lowest daily volume weighted average price over a five-day period after the notice.
The company said each drawdown would be up-to the greater of 200 percent of the average daily traded value for the five days before the drawdown request, or $5,000,000.
Anteris said a $500,000 commitment fee would be payable to the investor with $250,000 of the fee settled in ordinary shares or cash.
Anteris said each placement would use its existing placement capacity under ASX Listing Rules 7.1 or 7.1A.
Anteris fell $2.16 or 8.2 percent to $24.04.

GENETIC TECHNOLOGIES

Genetic Technologies says it hopes to raise $US5 million ($A7.22 million) through the issue of 3,846,155 American depository shares (ADS) at $US1.30 ($A1.88) per ADS.
Genetic Technologies said there were 600 Australian shares for each US ADS, which implied a cost per Australian share of 0.31 cents.
The company said it intended to use the funds for further product research and development, to increase its sales and marketing and other general corporate costs.
Genetic Technologies said New York's HC Wainwright was the exclusive placement agent for the offer.
Genetic Technologies fell 0.2 cents or 28.6 percent to 0.5 cents with 100.9 million shares traded.

RESPIRI

Respiri says its Wheezo remote patient monitoring (RPM) device will be reimbursed by Centres of Medicare and Medicaid Services (CMS) in the US.
The company said it had three current procedural terminology (CPT) reimbursement codes that covered the RPM products delivered through Access Telehealth and earning about $US124 ($A178.65) per patient, per month to the claiming physicians.
Respiri said it had monthly recurring revenues per patient when the Wheezo RPM program was delivered and reimbursed by CMS, in addition to device sales.
Respiri was unchanged at five cents.

UNIVERSAL BIOSENSORS

Universal Biosensors says it has delivered its first Xprecia Prime hand-held blood coagulation devices to Europe and made its first sales.

Last year, the company said it had Conformité Européenne (CE) mark approval for its prothrombin time, international normalized ratio (PT-INR) test to be sold in 32 countries that recognized the CE mark (BD: Feb 28,2022).

Today, Universal Biosensors chief executive officer John Sharman said it was a "significant a significant achievement … and something we have been anticipating for many months".

"It represents the beginning of our new coagulation business based around our next generation Xprecia Prime platform," Mr Sharman said.

"The sales performance for our coagulation business was extremely frustrating throughout 2022," Mr Sharman said.

"Even though Xprecia Prime was cleared for sale by European regulators in February 2022, supply chain issues meant that we could not get any stock delivered into Europe until now," Mr Sharman said.

"When we add the negative impact on sales of the unwinding of the Siemens Healthineers relationship, which continues to sell down its existing stockholding to meet market demand, sales for 2022 are low," Mr Sharman said.

"The Siemens relationship ends in March, our own distribution network is growing and our new Xprecia Prime device looks very promising in terms of sales," Mr Sharman said.

"The supply chain issues appear behind us, our US based clinical trial is complete and we are well positioned to submit our 510(k) application to have Xprecia Prime approved for sale in the US," Mr Sharman said. "We are looking forward to a much better sales performance from our coagulation business during 2023."

Universal Biosensors was up 2.5 cents or 8.2 percent to 33 cents.

IMMUTEP

Immutep says it has enrolled all 20 patients in its phase I, IMP321, triple combination therapy trial for non-small cell lung cancer (NSCLC).

In 2021, Immutep said it had dosed the first of up-to 20 patients in its first in-human, phase-I trial of 30mg subcutaneous doses of IMP321, or eftilagimod alpha or efti, every two weeks in conjunction with standard of care chemotherapy and anti-programmed death-1 (PD-1) therapy (BD: Aug 5, 2021).

Immutep fell one cent or 3.5 percent to 27.5 cents.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says it has a $1.3 million National Health and Medical Research Council grant to develop a diagnostic test to help eradicate malaria.

WEHI said that projects had received funding to translate a test that can detect people with 'hidden' Plasmodium vivax, considered the most widespread and resilient malaria parasite for its ability to remain dormant in the liver for years.

The Institute said the funding would support the development of the first point-of-care rapid diagnostic test and the deployment of a laboratory version in the Philippines.

WEHI said that $945,900 would be used to develop the rapid diagnostic and $361,800 would be used to deploy a high-throughput, laboratory version of the test in the Philippines to understand the cause of recent malaria outbreaks and for early detection of people at risk of carrying the silent parasite.

CRONOS AUSTRALIA (TO BE VITURA HEALTH)

Cronos says it has formally changed its name to Vitura Health with its ASX code to be changed to VIT from February 8, 2023.
Last year, Cronos said its annual general meeting voted to approve the name change and since its merger with CDA Health Pty Ltd (Cannabis Doctors Australia) it had worked to integrate the two businesses into one company (BD: Nov 29, 2022).
The company said that the Australian Securities and Investments Commission had altered the details of the company's registration to reflect the change of name.
Biotech Daily shall change the name with the ASX change.
Cronos was unchanged at 54 cents.

EMYRIA, WOKE

Emyria and Woke have welcomed the Australian Therapeutic Goods Administration's down-scheduling of 3,4 methylene-dioxy-meth-amphetamine (MDMA) and psilocybin.
Last week, the TGA said it would allow the prescription of psilocybin and MDMA "by specifically authorized psychiatrists" from July 1, 2023 (BD: Feb 3, 2023).
Today, Emyria said its "clinical service is well positioned to accelerate access to MDMA-assisted therapies" following the changes.
Emyria said the TGA's decision opened "a pathway to registration and reimbursement for MDMA and its analogues".
The company said the change would allow it to "collaborate with clinical partners to improve patient access and ongoing research while continuing the drug discovery program in Australia and the US to identify novel, MDMA-like compounds with the greatest therapeutic potential".
Emyria managing director Dr Michael Winlo said the company believed the TGA's decision would allow it "to build a stronger evidence base for treating mental health conditions with psychedelics and make a large and positive impact for patients".
Woke said following the TGA decision, it was "planning an educational initiative for specialist psychiatrists regarding psilocybin and its use for treatment-resistant depression".
The company said its WP002 25mg psilocybin tablet would "be made available to authorized prescribers … from July 1, 2023".
Woke chief executive officer Nick Woolf said "the down-scheduling of psilocybin for treatment-resistant depression demonstrates the TGA's commitment to novel treatment approaches".
"In [its] statement, the TGA referred to the relative safety and potential efficacy of psilocybin when used in a medically controlled setting."
"Woke is developing a novel psilocybin drug candidate, WP002, for treatment-resistant depression and other mental health disorders," Mr Woolf said.
Emyria was up 12 cents or 63.2 percent to 31 cents with 28.2 million shares traded.
Woke is a private company.