Biotech Daily

Monday December 12, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: KAZIA UP 7%; ACTINOGEN DOWN 10%**

*** IMRICOR $7.4m KAHR FOUNDATION CONVERTIBLE NOTE**

*** AVITA RECELL FDA SUPPLEMENT FOR SOFT TISSUE REPAIR**

*** NOVA EYE: 'NO ITRACK ADVANCE US APPROVAL THIS YEAR'**

*** NUHEARA INNERSCOPE TO DISTRIBUTE HP PRO SELF-FIT IN US**

*** IMUGENE: 'EARLY DATA BACKS CHECKVACC FOR BREAST CANCER'**

*** USCOM CHINA SUBSIDIARY AN 'INNOVATIVE ENTERPRISE'**

*** PHARMAUST $654k FEDERAL R&D TAX INCENTIVE; REPAYS RADIUM**

*** WOKE, SYDNEY UNI SIGN PSILOCYBIN ALCOHOLISM TRIAL**

*** PARADIGM US PPS PATENT FOR BONE MARROW DISEASES**

*** ANATARA EGM 47% OPPOSE ADVISOR OPTIONS**

*** RADIOPHARM CHAIR PAUL HOPPER DILUTED TO 28.7%**

*** MERCHANT TAKES 11.8% OF HEXIMA**

MARKET REPORT

The Australian stock market fell 0.45 percent on Monday December 12, 2022, with the ASX200 down 32.4 points to 7,180.8 points. Twelve of the Biotech Daily Top 40 stocks were up, 20 fell, six traded unchanged and two were untraded. All three Big Caps fell.

Kazia was the best, up 0.6 cents or 6.7 percent to 9.5 cents, with 320,766 shares traded. Patrys climbed 4.2 percent; Alcidion, Atomo and Opthea were up more than three percent; Compumedics, Genetic Signatures and Uscom rose two percent or more; Emvision and Neuren were up more than one percent; with Mesoblast and Polynovo up by less than one percent.

Actinogen led the falls, down 1.45 cents or 12.9 percent to 9.8 cents, with 6.9 million shares traded. Prescient lost 10.7 percent; Nanosonics was down 9.9 percent; Antisense and Universal Biosensors fell more than four percent; Paradigm lost 3.4 percent; Clinuvel, Impedimed, Oncosil and Volpara shed more than two percent; Cochlear, Cynata, Immutep, Medical Developments, Next Science, Orthocell, Pharmaxis, Pro Medicus, Proteomics and Telix were down one percent or more; with Avita, CSL and Resmed down by less than one percent.

IMRICOR MEDICAL SYSTEMS

Imricor says it will raise $US5 million ($A7.4 million) through the issue of a convertible note to the Minnetrista, Minnesota-based the Kahr Foundation.
Imricor said the convertible note had a maximum purchase price of $US5 million, in two tranches, with compound interest at 10 percent a year, maturing in four years.
The company said that the note could be converted at any time from 36 months after closing and up to the maturity date.
Imricor said that Kahr could require it to convert “some or all of the outstanding principal on the convertible note and the accrued and unpaid interest”.
The company said that the conversion price of the note would be 105 percent of the 10-day, volume-weighted average price of its Chess depositary interests (CDIs) on the date prior to entry into formal documentation.
Imricor said that Kahr would receive five-year options to purchase CDIs in an amount equal to 10 percent of the total amount invested in each tranche, divided by the conversion price.
The company said that it expected to enter into “formal documentation” on or before December 16, 2022 and would provide further details at that time.
Imricor said that the Kahr Foundation was “an existing substantial shareholder” but did not disclose its holdings.
Imricor was up half a cent or 1.3 percent to 39 cents.

AVITA MEDICAL

Avita says it has submitted a pre-market approval supplement to the US Food and Drug Administration for its Recell spray-on skin to include soft tissue repair.
In February, Avita said the FDA had approved a pre-market application supplement for its Recell “autologous cell harvesting” spray-on-skin device for the treatment of acute thermal burns (BD: Feb 18, 2022).
In August, the company said that although Recell significantly improved “donor sparing” in skin grafts for soft tissue reconstruction ($p < 0.001$), “the healing endpoint did not reach pre-specified statistical non- inferiority” but observed values for healing with Recell were the same or slightly better than control. (BD: Aug 12, 2022).
In November, Avita said an “updated analysis of data” from the 65-patient study of Recell spray-on skin for soft tissue reconstruction showed Recell met its healing non-inferiority endpoint (BD: Nov 10, 2022).
At that time, Avita said “further re-verification resulted in corrections to the healing data, ultimately leading to a conclusion of non-inferiority for healing”, with the non-inferiority endpoint for healing demonstrating statistical significance of $p < 0.025$.
Today, the company said that the premarket approval supplement included the recent results from the soft tissue repair trial, and followed the FDA breakthrough device designation for soft tissue repair and vitiligo in November (BD: Nov 4, 2022).
Avita said the pre-market approval supplement had a 180-day review timeline.
Avita chief executive officer Jim Corbett said “soft tissue repair encompasses a broad label of Recell applications and allows us to target all level one and level two trauma centres in the US”.
“Once approved, this indication expands our current market opportunity by at least three times and is expected to create a significant growth opportunity for us beginning July, 2023,” Mr Corbett said.
Avita fell half a cent or 0.3 percent to $1.955.

NOVA EYE MEDICAL

Nova Eye says it does not expect to receive US approval for its Itrack Advance canaloplasty device “prior to December 31, 2022, as previously stated”.

Nova Eye said that it had received “feedback” from the US Food and Drug Administration in relation to its 510(k) submission for its Itrack Advance which indicated it would not receive marketing clearance this year.

Previously, the company said the Itrack Advance was “designed to lower eye pressure and [might] reduce or eliminate the need for glaucoma eye drops” (BD: Jun 8, 2022).

Today, Nova Eye said that the original Itrack had been cleared by the FDA in 2008, and was currently “the only device in the US with an indication for canaloplasty”.

Nova Eye managing-director Tom Spurling said the company would “continue to progress our submission for the Itrack Advance”.

“We continue to have an excellent opportunity in the US with the original Itrack canaloplasty micro-catheter, because of growing surgeon interest in canaloplasty and a favorable reimbursement environment,” Mr Spurling said.

“Outside of the US, we will pursue sales of the Itrack Advance in the key markets of Germany, the UK, Italy, and Canada… [and] will also look to introduce Itrack Advance into additional markets, with several regulatory evaluations currently in progress,” Mr Spurling said.

Nova Eye was untraded at 29.5 cents.

NUHEARA

Nuheara says that the Sacramento, California-based Innerscope Hearing Technologies will market and sell its over-the-counter self-fit hearing aids in the US.

Nuheara did not disclose the commercial terms of the partnership with Innerscope but said the agreement would expand its points of sale from about 300, to about 4,600 “over the coming months”.

In October, the company said that the US Food and Drug Administration 510(k) had approved its self-fitting, over-the-counter Hewlett-Packard Hearing Pro hearing aid (BD: Oct 31, 2022).

Today, Nuheara said that Innerscope developed and marketed over-the-counter hearing aids and related hearing products and offered point-of-sale hearing screening kiosks in US pharmacies.

Nuheara said it would supply its hearing products to Innerscope at an agreed wholesale price and would receive an agreed royalty or service fee for the licencing of its self-fit technology into Innerscope products for US FDA self-fitting clearance.

The company said Innerscope would market the products at its cost, including to Walmart, Rite Aid and other pharmacy brands, and would be required to meet minimum order quantities in defined time periods.

Nuheara managing-director Justin Miller said the company was “delighted to enter into this partnership … significantly increasing Nuheara’s retail points of sale in the US”.

“Innerscope has been innovating the US hearing industry by bringing affordable hearing aid technology direct to US consumers,” Mr Miller said.

Mr Miller said that Innerscope product displays were at about 1,500 Walmart Vision Centers were selling over-the-counter hearing aids, and with the Hewlett-Packard Hearing Pro would begin selling US FDA cleared self-fitting hearing aids.

“Early next year Innerscope’s footprint will be expanded to 1,700 Rite Aid pharmacies, with further growth planned,” Mr Miller said.

Nuheara was up four cents or 19.05 percent to 25 cents.

IMUGENE

Imugene says early data from its phase I trial of Checkvacc for triple negative breast cancer shows safety and positive biomarker signals.

Imugene said the data was presented as a poster presentation, titled 'Phase I study of intra-tumoral administration of CF33-hNIS-antiPD-L1 (Checkvacc) in patients with metastatic triple negative breast cancer' at the San Antonio Texas Breast Cancer Symposium on December 9, 2022.

Imugene managing-director Leslie Chong said she was "encouraged that we are seeing positive signals with correlative biomarker and imaging data at such an early stage of our Checkvacc Phase I trial," Ms Chong said.

Imugene said CF33-humanised human sodium iodide symporter (hNIS)-anti-programmed death ligand-1 (PD-L1) administered by intra-tumoral injection in patients with metastatic triple negative breast cancer was "safe and well tolerated at the dose levels tested".

The company said six patients had received at least one dose of Checkvacc injection at either 100,000 particle-forming units (PFUs) or 300,000PFUs, with no dose-limiting toxicities observed and no treatment-related adverse events reported except for one patient with injection site discoloration.

The company said that technetium-99m (99-mTc) single-photon emission computed tomography (Spect) imaging for virus tracking from virus-induced replication of the human sodium iodide symporter (hNIS) transgene showed enhancement in four of six patients in the first two dose levels.

Imugene said that the enhancement "was greater in patients with injection of nodal disease compared to dermal metastasis".

The company said that imaging of one of the patients in the second dose level at day-8 "showed significant enhancement of injected lymph node" with baseline and treated tumor biopsies showing an increase in programmed death ligand-1 (PD-L1) positive cells.

Imugene said the increase in PD-L1 positive cells showed "immune activation and tumor micro-environment changes in association with response to therapy".

The company said that "taken together, these data support further evaluation of Checkvacc in [triple negative breast cancer]".

Imugene was unchanged at 18.5 cents with 15.6 million shares traded.

USCOM

Uscom says Beijing Chaoyang Development and Reform Committee has selected its subsidiary Beijing Uscom Consulting Co as one of the first innovative companies.

Uscom said that on November 25, 2022, the government-run Committee selected its subsidiary as "one of the first innovative small and medium-sized enterprises".

The company said that the designation referred to enterprises "with strong innovation ability in products, technologies, management and modes, focusing on market segments with good growth… [and] a high level of specialization, strong innovation ability and development potential".

Uscom chair Prof Rob Phillips said the selection was "further validation of Uscom's recognition in China as an influential innovator and as economic activities within China begin to rebound, Uscom is well positioned for growth and clinical uptake".

"Endorsements such as these demonstrate the regard in which Uscom, and specifically Uscom China, is held internationally and support its potential in the market," Prof Phillips said.

Uscom was up 0.1 cents or two percent to 5.1 cents.

PHARMAUST

Pharmaust says it has received $654,109 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Pharmaust said the rebate related to expenditure for the year to June 30, 2022.
The company said that it repaid its $229,400 Radium Capital loan (BD: May 17, 2022).
Pharmaust was unchanged at 6.9 cents.

WOKE PHARMACEUTICALS

Woke says it has a formal agreement with the University of Sydney for an up-to 60 patient, phase IIb trial of WP002 psilocybin for patients with alcohol use disorder.
In October, Woke said that it would fund the trial and provide 25mg psilocybin WP002 tablets for the trial which will examine the safety, tolerability and proof-of-concept efficacy of WP002, in combination with psychotherapy, for patients with alcohol use disorder, or alcoholism (BD: Oct 18, 2022).
Mr Woolf told Biotech Daily that the company expected to seek ethics approval in February 2023 and hoped to have results by January 2025.
Woke is a private company.

PARADIGM BIOPHARMA

Paradigm says the US Patent and Trademark Office has allowed a patent for its method to treat bone marrow diseases and injuries with pentosan polysulfate (PPS).
Paradigm managing-director Paul Rennie told Biotech Daily that the patent, titled 'Treatment of Bone Marrow Pathologies with Polysulfated Polysaccharides,' was expected to protect its intellectual property until February 2043.
Paradigm fell 4.5 cents or 3.4 percent to $1.265 with 826,598 shares traded.

ANATARA LIFE SCIENCES

Anatara says its extraordinary general meeting faced 47.33 percent opposition to the issue of 3,500,000 advisor options to Taylor Collison and Candour Advisory Pty Ltd.
Anatara said all other resolutions passed easily, but the resolution to issue 2,000,000 options to the Adelaide stockbroker Taylor Collison and 1,500,000 options to Adelaide corporate advisory firm Candour, exercisable at seven cents each by December 11, 2025, faced 11,023,632 votes (47.33%) against, and 12,269,453 votes (52.67%) in favor.
According to its most recent filing, Anatara had 97,050,120 shares on issue, meaning the votes against the advisor options amounted to 11.35 percent of the company, sufficient to requisition extraordinary meetings.
Anatara was untraded at 3.5 cents.

RADIOPHARM THERANOSTICS

Radiopharm chair Paul Hopper says his 94,221,428 share-holding has been diluted from 31.78 percent to 28.68 percent.
Mr Hopper said that he was diluted due to the issue of shares on November 25, 2022.
In November, Radiopharm said shareholders subscribed for $1.2 million of its $4.5 million underwritten retail offer, at 14 cents a share, with $5.5 million raised in the institutional offer, taking the total raised to $10 million (BD: Nov 22, 2022).
Radiopharm was unchanged at 11 cents.

HEXIMA

Merchant Group Australia Pty Ltd says it has increased its substantial holding in Hexima from 18,000,000 shares (10.78%) to 19,686,348 shares (11.79%).

The Perth-based Merchant said it bought 1,696,348 shares on December 9, 2022 for $29,766 or 1.8 cents a share.

Last week, Hexima requisitioned an extraordinary general meeting to remove Hexima directors Michael Aldridge, Jake Nunn and Scott Robertson and replace them with Merchant chief financial officer and company secretary Chris Mews (BD: Dec 5, 2020)

Hexima was untraded at 1.7 cents.