

Biotech Daily

Thursday April 20, 2023

Daily news on ASX-listed biotechnology companies

- * ASX FLAT, BIOTECH DOWN: AMPLIA UP 6%; KAZIA DOWN 11%
- * QUEENSLAND UNI DEVELOPS GOLD FILM SENSOR FOR DEVICES
- * HYDRIX 9-MONTH RECEIPTS UP 63% TO \$10.8m
- * CYCLOPHARM BUYS DUPHARMA FOR 100k SHARES, \$65k
- * BLUECHIIP: NY PSYCHIATRIC INSTITUTE BUYS CRYO LABELS
- * STARPHARMA: 'ADZ0466 33% TUMOR REGRESSION, IN MICE'
- * ARGENICA: 'ARG-007 REDUCES BRAIN INJURY 70%, IN RATS'
- * IMUGENE: 'CHECKVACC SAFE, WELL-TOLERATED'
- * ISRAEL APPROVES INVEX PRESENDIN IIH TRIAL
- * UNIVERSAL BIOSENSORS LAUNCHES 6th SENTIA TEST WINE ACIDITY
- * AROVELLA TELLS ASX: 'POSTER PUBLISHED AFTER 39% PRICE JUMP'
- * MESOBLAST REQUESTS 'PLACEMENT' TRADING HALT
- * RACE APPOINTS MARY HARNEY CHAIR; DR JOHN CULLITY DIRECTOR
- * HERAMED LOSES DIRECTOR TAL SLONIM, EXECUTIVE ADY JAKUBOVITZ

MARKET REPORT

The Australian stock market slipped 0.04 percent on Thursday April 20, 2023, with the ASX200 down 3.3 points to 7,362.2 points. Twelve of the Biotech Daily Top 40 stocks were up, 21 fell, six traded unchanged and one was untraded. All three Big Caps were up.

Amplia was the best, up 0.5 cents or 5.6 percent to 9.5 cents, with 31,295 shares traded; followed by Cyclopharm up 5.45 percent to \$2.13 with 10,736 shares traded. Actinogen, Imugene and Telix improved more than four percent; Patrys and Universal Biosensors were up more than three percent; Starpharma rose two percent; Dimerix and Proteomics were up more than one percent; with Clinuvel, Cochlear, CSL, Pro Medicus and Resmed up by less than one percent.

Yesterday's 18 percent best, Kazia, led the falls, down 2.5 cents or 10.9 percent to 20.5 cents, with 326,968 shares traded. Pharmaxis and Prescient lost more than eight percent; Atomo and Genetic Signatures were down more than five percent; Alcidion, Medical Developments, Next Science and Oncosil fell four percent or more; Emvision, Neuren, Nova Eye and Paradigm were down more than three percent; Antisense, Cynata and Polynovo shed more than two percent; Avita, Mesoblast, Micro-X and Nanosonics were down one percent or more; with Volpara down by 0.6 percent.

UNIVERSITY OF QUEENSLAND

The University of Queensland says it has developed a thin, gold, film biosensor that could be used for bio-monitoring and implantable medical implants.

The University's Australian Institute for Bioengineering and Nanotechnology's Aditya Ashok told Biotech Daily that the sensor's uses included monitoring glucose levels in the body and recording of nerve action potential.

Mr Ashok said the sensor was 20mm by 5mm by 0.01mm, and comprised four individual smaller parts that had a sensory area of 60 μ m.

The Institute said the "film-like" sensor was made of mesoporous materials, highly porous substances that could be used in diagnostics, catalysis and drug delivery.

The Institute's Dr Mostafa Kamal Masud said "our aim here is to see this sensor embedded in wearable devices ... but the potential and possibilities in this field are vast". "Although modern implanted electronics have developed rapidly over the past 60 years, most commercially available devices are still built on relatively similar - and limiting design concepts such as thick ceramic or titanium packaging," Dr Masud said.

<u>HYDRIX</u>

Hydrix says receipts from customers for the nine months to March 31, 2023 were up 63.0 percent from \$6,650,000 to \$10,842,000.

Hydrix said receipts for the three months to March 31, 2023 were up 107.8 percent from \$1,709,000 to \$3,552,000.

The company said it had a cash burn of \$929,000 for the three months to March 31, 2023 with cash and equivalents of \$1,891,000, and an estimated 2.04 quarters of funding. Hydrix was up 0.25 cents or 6.1 percent to 4.35 cents.

CYCLOPHARM

Cyclopharm says it has bought the Copenhagen-based medical distributer Dupharma Aps for 100,000 shares and an additional \$65,000 in cash.

Cyclopharm said Dupharma had sold its Technegas technology in Denmark for several years and its acquisition meant Cyclopharm had eight locations directly serving 18 of the 64 countries where Technegas was sold.

Cyclopharm chief executive officer James McBrayer said that "expanding our distribution network in the Nordic region with the Dupharma acquisition is strategically important and consistent with our global initiatives in the nuclear and respiratory medicine spheres." Cyclopharm was up 11 cents or 5.45 percent to \$2.13.

BLUECHIIP

Bluechiip says the New York Psychiatric Institute has placed initial orders for delivery of its cryogenic, sample management labels.

Bluechip said the Institute was a consortium of the New York State Psychiatric Institute, the Research Foundation for Mental Hygiene and the Columbia University Department of Psychiatry, all of which were based in New York city.

The company said the addition of the Institute increased its North American presence to 25 laboratories and 12 customers.

Bluechiip chief executive officer Andrew McLellan said "being partnered with a broad base of Ivy League research facilities further emphasizes Bluechiip's applications".

Bluechiip was up 0.3 cents or 11.5 percent to 2.9 cents.

STARPHARMA

Starpharma says its ADZ0466 formulation has shown tumor regression in eight out of 24 (or 33 percent) of small lung cancer patient-derived xenografts, in mice.

Starpharma said that 14 of the mouse models were patient-derived xenografts and 10 were circulating tumour cell-derived xenografts.

The company said AZD0466 was a "highly optimized dendrimer nanoparticle formulation of an Astrazeneca drug" using its technology to improve solubility, efficacy, pharmaco-kinetics, targeting and reduce toxicities".

Starpharma said AZD0466 outperformed Venetoclax and was active in models resistant to platinum or etoposide chemotherapy, the current standard-of-care treatment.

In addition to the cancer models, the company said three of nine patients had shown tumor regression, with "stable disease" achieved for up to 5.5 months in its trial of ADZ0466 for advanced solid tumors including adrenal carcinoma, anal cancer, bile duct cancer, bladder/urethral cancer, lung cancer, pancreatic and sarcoma. Starpharma was up one cent or two percent to 51 cents.

ARGENICA THERAPEUTICS

Argenica says a single 300 nmol/kg dose of ARG-007 reduces hypoxic ischaemic encephalopathy by more than 70 percent in rats.

Argenica said ARG-007 maintained the reduction in brain injury caused by both ischemia (reduced blood flow) and vasogenic oedema (brain swelling) from one to four weeks post injury, with a 73.96 percent reduction at one week and 70.3 percent at four weeks. The company said doses of 100 and 300 nmol/kg also reduced brain swelling 48 hours after injury by 35.4 and 32.9 percent respectively.

Argenica said it was completing pre-clinical studies for an investigational new drug application to the US Food and Drug Administration.

The company said it was in talks with Labcorp to develop a regulatory and clinical strategy for ARG-007 for hypoxic ischaemic encephalopathy in newborns.

Argenica said it had started a pre-clinical juvenile toxicology study and pre-clinical efficacy studies in a large animal model of hypoxic ischaemic encephalopathy, and pending positive results, the company hoped to begin a US phase I/II trial. Argenica fell 3.5 cents or 7.6 percent to 42.5 cents.

IMUGENE

Imugene says its Checkvacc oncolytic virotherapy for triple negative breast cancer is safe and well tolerated at three different dose levels.

Last year, Imugene said it had dosed the first patient in the third cohort of its dose escalation phase I trial of Checkvacc, or CF33-humanised sodium iodide symporter-anti-programmed death ligand-1 (CF33-hNIS-anti-PDL1) (BD: Aug 10, 2022).

Today, the company said its single-photon emission imaging, which allowed it to track where the virus was replicating in real time, showed an "enhancement" in 75 percent of injected lesions following treatment with Checkvacc.

Imugene said the data was "the first known report of successful hNIS-based imaging to track oncolytic poxvirus replication in humans".

Imugene chief executive officer Leslie Chong said that "while it was pleasing to see the primary objective of safety and tolerability of Checkvacc confirmed, the imaging data presented showed several other positive outcomes resulting from our first-in-human trial." Imugene was unchanged at 14 cents with 16.5 million shares traded.

INVEX THERAPEUTICS

Invex says it has Israel ethics approval for its 240-patient, phase III 'Evolve' trial of Presendin for idiopathic intracranial pressure.

Invex said the randomized, placebo-controlled, double-blind trial activate up-to nine clinical sites in Israel to determine the efficacy and safety of Presendin versus placebo, administered once weekly over 24 weeks.

The company said that the trial's primary endpoint was the change in intracranial pressure from baseline, with key secondary endpoints related to vision and headache outcome measures.

Invex said it intended to open up-to 40 clinical sites in total.

Last year, Invex said that the first patients in the phase III trial had been randomized in the study and it had trial approvals in the Australia, the US, the UK, Germany and New Zealand (BD: Nov 21, 2022).

Invex fell two cents or 4.3 percent to 44.5 cents.

UNIVERSAL BIOSENSORS

Universal Biosensors says it will sell a wine acidity test through its website, the sixth wine analysis product under its Sentia brand.

Universal Biosensors said the test would measure titratable acidity, which was tested throughout the year and contributed to the taste and stability of wine, influencing harvest times and decisions related to wine color, stability and flavor profile.

Universal Biosensors chief executive officer John Sharman said that current testing relied on "traditional enzymatic tests using expensive machinery and time consumer process or simple color changes on enzymatic paper strips."

Mr Sharman said Sentia sales for the three months to March 31, 2023 were up 188 percent compared to the previous corresponding period, and that an estimated 16 percent of Australian wineries used Sentia products.

Universal Biosensors was up one cent or 3.6 percent to 29 cents.

AROVELLA THERAPEUTICS

Arovella has told an ASX 'Aware' query a poster featuring results from its ALA-101 for leukaemia study was printed on April 15, 2023, following a 39.3 percent price rise. Last Friday, Arovella told the ASX it was not aware of any information that could explain a 39.3 percent price rise from 5.6 cents on April 11 to 7.8 cents on April 14, , but said that on February 6, it had told the ASX it was scheduled to present at the American Association for Cancer Research on April 16 (BD: Apr 14, 2023).

On Monday, the company said ALA-101 showed "significant" anti-tumor effect in mice and could have the potential to be an on off-the-shelf treatment for leukemias and lymphomas (BD: Apr 17, 2023).

Today, Arovella said the poster was "akin to a research article, in that in isolation the data from an individual experiment may not but meaningful ... [but] with other data sets ... the data can be interpreted and meaningful conclusions can be drawn from the results".

The company said the data featured on the poster, printed the day before the conference on Saturday April 15, 2023 (US EDT) "comprised data from multiple experiments collected over time" and was being finalized and analyzed up to April 15.

Arovella said that after presentation of the poster at the conference and before the market opened, a copy was released to the market, along with a brief interpretation of the results. Arovella was up 0.1 cents or 1.5 percent to 6.8 cents with 12.4 million shares traded.

MESOBLAST

Mesoblast has requested a trading halt pending an announcement "in relation to a proposed private placement of securities to targeted investors". Trading will resume on April 24, 2023 or on an earlier announcement. Mesoblast last traded down one cent or one percent to 99 cents.

RACE ONCOLOGY

Race says it has promoted non-executive director Mary Harney to chair, effective immediately, with Dr John Cullity continuing as a non-executive director.

Race said Ms Harney had been director since February 8, 2021.

The company said Ms Harney was chair of Oncology One and Microbio, and was previously the Royal Australasian College of Surgeons chief executive officer and Gardiner Dairy Research Foundation chief executive officer, as well as Breakthrough Victoria Fund interim chief executive officer and Peter MacCallum Cancer Centre chief operating officer.

According to her LinkedIn, Ms Harney held a Bachelor of Science from Monash University and a Bachelor of Arts from the University of Melbourne.

Race fell one cent or 0.5 percent to \$1.905.

HERAMED

Heramed says non-executive director and co-founder Tal Slonim has "agreed to leave the board" and business development head Ady Jakubovitz has resigned.

Heramed said Anoushka Gungadin would transition from part-time to full-time director of strategic partnerships for Australia and New Zealand.

The company said that although the focus of the company was on technology design, development and manufacturing, it had evolved to commercialization and scaling up resources to generate sales.

Heramed co-founder David Groberman said Mr Slonim was "until recently, the chief operating officer and an executive director and his significant knowledge, hands-on capabilities, and deep experience in system design have been hugely valuable in the success of Heramed to date".

"I wish both Tal and Ady all the best with their future business interests and thank them for their contribution," Mr Groberman said.

Heramed was unchanged at 10 cents.