



Biotech Daily

Tuesday May 2, 2023

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: MICRO-X UP 21%; ONCOSIL DOWN 8%**
- * **TELIX: TLX250-CDX IMAGES 'VERY SMALL KIDNEY CANCER LESIONS'**
- * **POLYNOVO 1st US NOVOSORB MTX SALES, RECORD \$6m MONTH**
- * **RADIOPHARM RAD301 TARGETS TUMORS**
- * **INCANNEX IHL-675A ADVERSE EVENTS EQUALS CBD, MORE THAN HCQ**
- * **AVECHO RECEIVES \$687k FEDERAL R&D TAX INCENTIVE**
- * **ONCOSIL CUTS STAFF, COSTS**
- * **HYDRIX TO DISTRIBUTE ECHO IQ ECHOSOLV HEART TEST**
- * **VITURA, PHARMALA 'CORTEXA' PSYCHEDELIC JOINT VENTURE**
- * **NEUROTECH 5.4m COO OPTIONS EGM**
- * **CRESO 'MELODIOL' NAME CHANGE, 15.5m SHARES, 47.8m OPTIONS AGM**
- * **KINGSLEY HALL REPLACES MICRO-X CEO PETER ROWLAND, DIRECTOR**

MARKET REPORT

The Australian stock market fell 0.92 percent on Tuesday May 2, 2023, with the ASX200 down 67.2 points to 7,267.4 points. Fifteen of the Biotech Daily Top 40 stocks were up, 18 fell, five traded unchanged and two were untraded. All three Big Caps fell.

Micro-X was the best, up two cents or 21.05 percent to 11.5 cents, with 895,953 shares traded. Impedimed and Uscom improved more than 12 percent; Orthocell and Telix climbed more than three percent; Clinuvel, Mesoblast, Neuren, Next Science, Paradigm and Prescient rose two percent or more; Atomo, Avita and Immutep were up more than one percent; with Pro Medicus up by 0.6 percent.

Oncosil led the falls, down 0.1 cents or 8.3 percent to 1.1 cents, with 2.8 million shares traded. Patrys lost 7.1 percent; Compumedics was down 6.25 percent; Antisense shed 5.3 percent; Emvision fell 4.6 percent; Cynata, Genetic Signatures, Imugene, Medical Developments, Proteomics and Resmed were down three percent or more; Alcidion, Kazia, Opthea and Resonance shed more than two percent; Cyclopharm and Volpara were down more than one percent; with Cochlear, CSL, Nanosonics and Polynovo down by less than one percent.

TELIX PHARMACEUTICALS

Telix says further phase III TLX250-CDx trial data shows that for renal lesions of 2.0cm or less, sensitivity was 84 percent, with specificity from 92.3 percent to 100 percent. Last year, Telix said its 300-patient, phase III trial of TLX250-CDx for imaging clear-cell renal cancer met its primary endpoints, with 86 percent sensitivity and 87 percent specificity, with the “key secondary endpoint” of commensurate sensitivity and specificity of detecting clear-cell renal cancer in tumors of less than 4.0cm in diameter “currently a significant clinical challenge” (BD: Nov 7, 2022).

The company said at that time that it had agreed with the US Food and Drug Administration that a sensitivity and specificity threshold of 70 percent would be the confirmatory trial objective, and that was the study goal.

Yesterday, Telix said TLX250-CDx, 89-zirconium-deferoxamine-girentuximab, with positron emission tomography (PET) and computed tomography (CT) imaging for clear cell renal cell carcinoma (ccRCC), confirmed the “utility and effectiveness in very small renal masses, which are prevalent and present a significant diagnostic challenge”.

The company said that the data was presented at the American Urological Association meeting in Chicago on April 30, 2023 by the University of California Los Angeles Institute of Urologic Oncology kidney cancer program director Prof Brian Shuch a principal investigator in its phase III Zircon study.

Telix described tumors of 2.0cm or smaller as “very small renal lesions” and the data reinforced the accuracy of TLX-CDx across all analyses.

Telix chief medical officer Dr Colin Hayward said that “the excellent sensitivity and specificity for small lesions considerably expands the clinical utility and potentially the commercial opportunity for TLX250-CDx”.

“We expect that that the ability to diagnose even very small lesions as ccRCC will be an important factor in driving market adoption, subject to product approval,” Dr Hayward said. Prof Shuch said that for very small renal masses “the data set still shows outstanding sensitivity and specificity, far exceeding confirmatory trial success targets”.

“This data is meaningful for surgeons to help them improve management by aiding risk stratification, selecting appropriate patients for treatment or in those where further imaging [and/or] biopsy could be indicated,” Prof Schuch said.

Telix said it was “in the process of implementing an expanded access program in the United States and establishing named patient programs for TLX250-CDx in Europe”.

Telix was up 32 cents or 3.1 percent to \$10.78 with 2.1 million shares traded.

POLYNOVO

Polynovo says it has its first sales of its Novosorb MTX wound product in two separate US hospitals and has unaudited record monthly revenue of \$6.4 million.

Last year, Polynovo said it had US Food and Drug Administration 510(k) clearance for Novosorb MTX (matrix) for complex wounds (BD: Sep 19, 2022).

At that time, Polynovo chief executive officer Swami Raote said MTX was essentially Novosorb biodegradable temporizing matrix (BTM) “without the temporizing laminate”.

Today, Polynovo said it had record unaudited monthly revenue in March of \$6.4 million, up 48.2 percent compared to the previous corresponding period.

Polynovo chair David Williams said Novosorb MTX sales would be “lumpy for some time, but the trajectory is clear, and we see exciting times ahead in multiple jurisdictions”.

“We believe the quick first sales we have had in India, Canada, and Hong Kong are a good indicator of early adoption by surgeons,” Mr Williams said.

Polynovo fell 1.5 cents or 0.9 percent to \$1.615 with 7.7 million shares traded.

RADIOPHARM THERANOSTICS

Radiopharm says a 20-patient study of RAD301 for head and neck and pancreatic cancer showed radio-tracer uptake in tumors and no uptake in healthy tissue.

The research article, titled 'Validation of In-House Kit-Like Synthesis of ^{68}Ga -Trivehexin and Its Biodistribution for Targeting the Integrin $\alpha\beta_6$ Expressing Tumors' was published in Cancer Biotherapy and Radiopharmaceuticals, with an abstract available at:

<https://www.liebertpub.com/doi/10.1089/cbr.2022.0080>.

The abstract said that Ga-Trivehexin, synthesized from RAD301, was safe, reproducible, and cost-effective as an agent for non-invasive molecular imaging of integrin $\alpha\beta_6$ expressing tumors.

Radiopharm managing director Riccardo Canevari said in an email not released to the ASX the study was "pleasing evidence of the impact of this piece of our pipeline, [of] which we are eager to continue development".

Radiopharm fell three cents or 15 percent to 17 cents with 1.1 million shares traded.

INCANNEX HEALTHCARE

Incannex its IHL-675A combination cannabidiol and hydroxychloroquine had the same number of adverse events as Epidiolex but more than hydroxychloroquine.

Last year, Incannex said it completed dosing its 36-patient phase I trial of IHL-675A as a multi-use anti-inflammatory and the IHL-675A combination of cannabidiol and hydroxychloroquine was "well tolerated, with no adverse events of concern reported to date" (BD: Oct 13, 2022).

Today, the company said that treatment emergent adverse events "included abdominal pain, dizziness, fatigue, frequent bowel movements, headache and somnolence ... [and all events] were minor with the exception of one incidence of moderate severity abdominal cramps which resolved soon after on-set.

A chart provided by Incannex showed that both IHL-675A and the cannabidiol Epidiolex had more than 30 percent of subjects reporting an event but less than 10 percent of those administered the hydroxychloroquine sulphate Plaquenil reported an event.

The company said that the average pharmaco-kinetics of cannabidiol in participants administered IHL-675A compared to those administered Epidiolex showed that the cannabidiol was taken up from IHL-675A 26 percent more quickly and reached a 1.57 times higher maximum concentration than from Epidiolex.

Incannex said that the safety and pharmacokinetic data from the phase I trial "adds to the company's confidence in proceeding with assessment of IHL-675A in patients with inflammatory diseases".

Incannex said it was planning a 120-participant, randomized trial of IHL-675A for rheumatoid arthritis.

The company said that participants would be randomized to IHL-675A, cannabidiol alone, hydroxychloroquine alone or placebo, with the primary endpoint pain and function relative to baseline at 24 weeks.

Incannex fell half a cent or 4.2 percent to 11.5 cents with 6.5 million shares traded.

AVECHO BIOTECHNOLOGY

Avecho says it has received \$687,288 from the Australian Taxation Office under the Federal Government Research and Development Tax Incentive Program.

Avecho said the incentive related to expenditure for the year to December 31, 2022.

Avecho was up 0.05 cents or 10 percent to 0.55 cents.

ONCOSIL MEDICAL

Oncosil says it hopes to save \$1.1 million in annualized costs by reducing staff and other operational expenditure.

Oncosil said the rationalization followed a review of its expenditure and management would continue its review to ensure costs were “further aligned with company growth initiatives and managed in a sustainable way to extend the future cash runway”.

Oncosil chief executive officer Nigel Lange said the rationalization was “a challenging but necessary decision to ensure that Oncosil continues to allocate funds in a more sustainable way and provide better outcomes for shareholders by reducing our cash burn”.

“Our people are our biggest asset, and we will continue to support our team through this period of change,” Mr Lange said.

Oncosil fell 0.1 cents or 8.3 percent to 1.1 cents with 2.8 million shares traded.

ECHO IQ, HYDRIX

Echo IQ says it has partnered with Hydrix to sell its Echosolv artificial intelligence technology for detecting high risk structural heart disease patients.

Echo IQ said that Echosolv was an internet-cloud-based technology that used artificial intelligence to analyze and assess the risk of electrocardiogram data and supported improved diagnosis and faster time to treatment of heart diseases.

The company said the initial three-year agreement with Hydrix Medical Pty Ltd gave Hydrix exclusive rights to promote, market and sell the device in Australia, New Zealand and Singapore, and Hydrix would receive a commission on each customer it facilitated. Hydrix said it would receive a portion of commission upfront after Echo IQ completed the initial customer implementation, with the remainder received on the “contract anniversary date” to the end of the contract period based on recurring fees payable by the customer. Echo IQ was unchanged at 15 cents.

Hydrix was unchanged at 3.7 cents with 1.1 million shares traded.

VITURA HEALTH (FORMERLY CRONOS AUSTRALIA)

Vitura says it has a 50-50 joint venture with Toronto’s Pharmala Biotech, called ‘Cortexa Pty Ltd’, to produce and supply psychedelics for Australian research and clinical use.

Vitura said Cortexa would use Vitura’s industry relationships to distribute Pharmala produced 3,4-methylene-dioxy-meth-amphetamine (MDMA) and psilocybin in Australia.

The company said Cortexa would be owned equally and would pay Pharmala a \$250,000 annual licence fee for three years for its manufacturing technology and intellectual property and five percent royalty on net profits.

Vitura said it would pay a break fee of \$500,000 if the agreement was terminated and would advance up-to \$2,200,000 for working capital in loans at five percent a year.

Vitura chief executive officer Rodney Cocks said the objective of Cortexa was to establish “the leading MDMA and psilocybin supplier in the Australian market”.

“We are looking forward to working with the Pharmala team to bring a number of new ... treatment options to market at a time when major changes have been made to patient access to psychedelics in Australia,” Mr Cocks said.

Vitura said that Pharmala was expected to be “the first company in the world able to supply both [good manufacturing practice] MDMA and Psilocybin ready for prescription use in Australia”.

Vitura was up 1.5 cents or 4.05 percent to 38.5 cents.

NEUROTECH INTERNATIONAL

Neurotech says its extraordinary general meeting will vote to issue 5,416,667 options to chief operations officer Dr Alexandra Andrews and ratify a placement.

Neurotech said shareholders would vote to issue 5,416,667 options to Dr Andrews, in lieu of 15,000,000 options issued to Dr Andrews last year in her role as chief executive officer. The company said Dr Andrews would be issued the options in three tranches of 2,500,000 options at 8.0 cents, 1,666,667 options at 12 cents and 1,250,000 options at 16 cents, all exercisable by March 10, 2024.

Neurotech said shareholders would vote to issue 5,000,000 options exercisable at 10 cents within three years to the estate of the late Prof Allan Cripps as part of an "equity-based component to his remuneration package".

Neurotech said the meeting would also vote to issue 10,000,000 options exercisable at 13.5 cents to Max Capital under a corporate advisory mandate.

The company said it would vote to ratify the issue of 90,000,000 shares and 44,999,994 placement options under two placements last year.

Neurotech said that the meeting would vote to issue 10,000,000 options to placement managers PAC Partners Securities Pty Ltd and Peloton Capital Pty Ltd.

The meeting will be held at the offices of BDO Australia, Level 9, Mia Yellagonga Tower 2, 5 Spring Street, Perth on May 30, 2023 at 3:30pm (AWST).

Neurotech was unchanged at five cents.

CRESO PHARMA

Creso says its annual general meeting will vote to change its name to Melodiol Global Health and issue shares and options to related parties of the company.

Creso said investors would vote to issue 4,000,000 shares to chief financial officer Chris Grundy.

The company said that shareholders would vote to issue 2,000,000 options exercisable at 4.0 cents to director Benjamin Quirin.

The company said the meeting would vote to issue 4,000,000 shares to Everblu Capital Corporate Pty Ltd as lead manager to a placement.

Creso said it would issue 132,859,360 listed and 132,859,360 unlisted broker options to Everblu as placement lead managers, with the options exercisable at eight cents and three cents by January 31, 2027 and August 24, 2024, respectively.

Creso said the meeting would vote to issue 74,125,134 restructuring fee options to Everblu and a further 100,000,000 options to Everblu as lead manager fees for convertible notes raise, exercisable at eight cents each by January 31, 2027.

The company said shareholders would vote to issue 26,407,381 investor options exercisable at eight cents by January 31, 2027, to La Plata in exchange for \$US1,282,500 of debt owed.

Creso said the meeting would vote to issue 7,500,000 performance shares to chief executive officer and managing director William Lay for reaching milestones as well as issue 10,000,000 options exercisable at 20 cents by January 17, 2024.

The meeting will be held virtually on May 31, 2023 at 3pm (AEST).

Creso fell 0.1 cents or 9.1 percent to one cent with 17.1 million shares traded.

[MICRO-X](#)

Micro-X says it has appointed Kingsley Hall as chief executive officer replacing Peter Rowland who continues as a non-executive director.

Micro-X said Mr Hall had been chief financial officer and company secretary since February 2020 and his appointment as chief executive officer came at a time when the company “identified the need for a shift of emphasis from technical to commercial leadership”.

The company said it had appointed Anthony Skeats as chief operating officer and Brian Gonzales as chief executive officer of the Americas and chief scientific officer.

Micro-X said the appointments came at “a critical time ... as it prepares for the final steps to commercially launch of its first security product the Argus [improvised explosive device] x-ray camera” in the US.

Micro-X said Mr Rowland founded the company in September 2011 and had led it “to become a global leader in revolutionary x-ray imaging technology” and would assist the company as a non-executive director until the annual general meeting in November, 2023.

Micro-X chairman David Knox thanked Mr Rowland for his significant contribution as founder and chief executive officer and said, “on behalf of the whole board of directors and staff at Micro-X, I cannot thank Peter enough for bringing the company this far”.

Micro-X was up two cents or 21.05 percent to 11.5 cents.