



Biotech Daily

Monday April 15, 2024

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: NEXT SCIENCE UP 12%; PROTEOMICS DOWN 7%**
- * **FEDERAL MEDICAL SCIENCE CO-INVESTMENT PLAN**
- * **MONASH UNIVERSITY, SEAPORT: \$154m RAISED FOR GLYPH**
- * **CSIRO OPENS 1st 'INNOVATE TO GROW' SME COHORT**
- * **ATOMO: VIATRIS ORDERS \$570k MYLAN HIV TESTS**
- * **AUSTCO WINS \$2.2m TACERA SIMCOE VILLAGE CONTRACT**
- * **ADHERIUM: FDA OKAYS HAILIE FOR ASTRAZENECA AIRSUPRA, BREZTRI**
- * **INOVIQ SIGNS EXO-NET DISTRIBUTION DEAL WITH PROMEGA**
- * **ACTINOGEN TREATS 1st PHASE IIb XANAMEM ALZHEIMER'S PATIENT**
- * **CORRECTION: ONCOSIL MEDICAL**
- * **IMUGENE EXPANDS BILE TRACT CANCER TRIAL**
- * **OSTEOPORE RESPONDS TO ASX 790% PRICE, AWARE QUERY**
- * **ORTHOCELL RECEIVES \$3m FEDERAL R&D TAX INCENTIVE**
- * **ZELIRA RECEIVES \$919k FEDERAL R&D TAX INCENTIVE**
- * **RADIOPHARM EGM: UP-TO 12% OPPOSE LIND PARTNER STOCK**
- * **MICRO-X REQUESTS 'CAPITAL RAISING' TRADING HALT**
- * **NEUROTECH REQUESTS 'TRIAL RESULTS, CAPITAL RAISE' TRADING HALT**
- * **CLARITY DIRECTOR DR CHRIS ROBERTS, CABBIT, ROBWILL DILUTED TO 5.9%**
- * **CLARITY CHAIR DR ALAN TAYLOR BELOW 5%**
- * **CSIRO APPOINTS KIRSTEN ROSE DEPUTY CHIEF EXECUTIVE**
- * **PETER VAUGHAN REPLACES CLINUVEL 19-YEAR CFO, CO-SEC DARREN KEAMY**
- * **DORSAVI LOSES DIRECTOR CAROLINE ELLIOT**

MARKET REPORT

The Australian stock market was down 0.46 percent on Monday April 15, 2024, with the ASX200 down 35.6 points to 7,752.5 points. Eight of the Biotech Daily Top 40 stocks were up, 22 fell, seven traded unchanged and three were untraded. All three Big Caps fell.

Next Science was the best, up four cents or 11.8 percent to 38 cents, with 145,227 shares traded. Cynata climbed 8.1 percent; Actinogen was up 6.45 percent; Atomo and Nanosonics were up more than three percent; Orthocell rose 1.3 percent; with Clinuvel, and Genetic Signatures up by less than one percent.

Proteomics led the falls, down eight cents or 6.6 percent to \$1.14, with 343,085 shares traded. Avita and Resonance lost more than six percent; Universal Biosensors was down five percent; Dimerix, Immutep, Opthea and Prescient fell four percent or more; Impedimed, Mesoblast, Nova Eye, Paradigm and Starpharma were down more than three percent; Alcidion shed 2.2 percent; 4D Medical, Clarity, CSL, Imugene, Medical Developments, Neuren, Pro Medicus and Resmed were down more than one percent; with Cochlear, Emvision and Telix down by less than one percent.

FEDERAL GOVERNMENT

The Federal Government says it has identified investment opportunities, including medical devices, vaccines and personal protective equipment.

A media release from the Federal Minister for Industry and Science Ed Husic and Federal Minister for Health Mark Butler said the “medical science co-investment plan” outlined how government and industry could work together on opportunities in medical manufacturing. The Government said the plan included ways to build on advantages in clinical trial capabilities and therapeutic expertise in oncology, immunology, neurology and cardiovascular disease.

The media release said Australia’s health and medical research was “outperforming” ranked seventh globally, but medical manufacturing accounted for 0.3 percent of GDP. The Government said the medical science co-investment plan was the first of seven investment plans for Australia’s national reconstruction fund’s priority investment areas. Mr Ed Husic said that “great ideas can help create great products and great jobs”.

“But too many great Australian ideas have left our shores only to return as an import from another country,” Mr Husic said.

“Gardasil is a prime example of the terrible cost of lost opportunity, brilliant Australian medical research ended up being manufactured overseas because we didn’t have the capabilities to make it here,” Mr Husic said.

“As the National Reconstruction Fund works to revitalize manufacturing in key priority areas, we need a clear picture of the challenges and opportunities we face in each sector,” Mr Husic said. “This and the other co-investment plans to come underpin our commitment to a Future Made in Australia, giving us a guide to what we can do to boost sovereign capability and tackle supply chain challenges.”

In a separate announcement, Ausbiotech said it welcomed the medical science co-investment plan, having participated in the industry working group.

Ausbiotech interim chair Dr James Campbell said that the Co-Investment Plan “outlines the unique environment [in which] companies developing life-enhancing and life-saving technologies operate”.

For details, go to: <https://www.industry.gov.au/MedicalScienceCo-investmentPlan>.

[MONASH UNIVERSITY, SEAPORT THERAPEUTICS](#)

Monash University says Puretech spin-out Seaport Therapeutics has received \$US100 million (\$A154 million) to develop its Monash-developed Glyph drug delivery platform. Last year, Monash University said with Boston's Puretech Health, it developed the Glyph technology for oral administration of drugs with low oral bioavailability (BD: Feb 15, 2023). Today, the University said the funding came from a Series A financing round, with funding led by Arch Venture Partners and Sofinnova Investments, as well as Third Rock Ventures and Seaport's founder Puretech Health.

Monash said the risk of liver toxicity from neuropsychiatric medicines for disorders including depression and anxiety was holding back the development of such drugs, and said the Glyph platform aimed to address this by administering the drugs orally. The University said that the Glyph platform "solves these limitations by rerouting the mechanism of absorption to enable oral administration and reduce liver exposure". The Monash Institute of Pharmaceutical Sciences' Prof Christopher Porter said it was "rewarding to see the Glyph technology being used to attempt to unlock the full potential of neuropsychiatric medicines and make much-needed treatments easier, more effective and more accessible for those living with a broad range of neurological conditions".

[COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION](#)

CSIRO says it has opened its 'Innovate to Grow' online program's first cohort, called "Advanced Manufacturing" for small to medium-sized enterprises (SME).

In January, CSIRO said its 'Innovate to Grow' 10-week, free online program was launched in 2020 to help small-to-medium sized businesses with research and development (BD: Jan 22, 2024).

Earlier this month, the Organisation said it would provide \$20 million in funding to support up-to 750 small to medium enterprises and their research and development opportunities through its SME Connect team (BD: Apr 3, 2024).

Today, CSIRO said the Advanced Manufacturing cohort of its program was open to businesses working in biomedical, additive and natural products manufacturing as well as robotics, advanced materials and processes, sensing and detecting technologies, mechatronics design and engineering, energy storage and battery technology.

The Organisation said the program was for companies beginning early-stage research and development or "those venturing into new solutions within advanced manufacturing", with participants able to access experts and experienced researchers.

CSIRO said with the program would help participants formulate a research question, assess its impact, seek out strategic partnerships and develop a research and development business case and funding proposal.

CSIRO director of manufacturing Marcus Zipper said "advanced manufacturing is a vitally important sector, employing over 800,000 people across Australia".

"It's an exciting area of research and development for CSIRO, and we work collaboratively to connect [small-to-medium enterprises] with new technologies to improve efficiency, productivity, health, safety and environmental outcomes, while driving prosperity across the manufacturing sector," Mr Zipper said.

"We translate research into products and processes that businesses want to adopt because what we've created is economically viable, more efficient and effective, and sustainable," Mr Zipper said.

The Organisation said applications would close on May 12, 2024, with more details and applications available at: <https://bit.ly/3Q45LN4>.

ATOMO DIAGNOSTICS

Atomo says the Pittsburgh, Philadelphia-based Viatris Healthcare Pty Ltd has bought \$570,000 worth of its Mylan human immunodeficiency virus (HIV) self-tests.

Atomo said it would manufacture the order in the coming months and it considered “the revenue from these orders to be material.

The company said Viatris would supply the tests to “low and middle-income countries”.

Atomo managing-director John Kelly said the company was “delighted to see Viatris, our global health partner, continues to secure orders across low and middle-income country markets”.

“Recent growth in our global health markets mirrors anticipated growth here in Australia from emerging public health channels, and we are encouraged by the ongoing transition of diagnostic testing demand from healthcare facilities to self-test channels,” Mr Kelly said.

Atomo was up 0.1 cents or 3.3 percent to 3.1 cents with 11 million shares traded.

AUSTCO HEALTHCARE

Austco says it has a \$2.2 million contract to supply its Tacera alarm management and clinical workflow product to the Beeton, Ontario-based Simcoe Village.

Austco said Simcoe Village long-term care centre was being redeveloped and would have 160 long-term care beds plus 179 seniors housing units, including affordable housing for older adults, supportive housing and co-housing.

The company said the facility was owned and operated by the County of Simcoe and was expected to be completed around July 2025.

Austco said the “significant contract” included real-time location systems for automatic staff presence, automatic alarm cancellation and emergency staff duress, as well as its Pulse Mobile, enterprise reporting and clinical workflow solution.

The company said it expected revenue recognition from the contract to begin by July 2024, and that it increased its contracted orders yet to be delivered to a record \$45.7 million.

Austco managing-director Clayton Astles said the “contract award underscores the strength of Austco’s product offering and commitment to driving innovation in healthcare”.

Austco was up half a cent or 2.6 percent to 19.5 cents.

ADHERIUM

Adherium says the US Food and Drug Administration (FDA) has cleared its Hailie smart inhaler for use with Astrazeneca’s Airsupra and Breztri inhalation medication.

Adherium said Airsupra was “the first FDA-approved rescue medication for asthma patients” while Breztri was a triple combination medication for chronic obstructive pulmonary disease.

The company said the compatibility with Breztri gave it “100 percent coverage” for triple-therapy inhalers in the US.

Adherium said the approval was “a significant milestone in the management of asthma and chronic pulmonary disease, offering patients and healthcare providers enhanced monitoring capabilities and personalized treatment approaches”.

Adherium fell 0.2 cents or five percent to 3.8 cents with 78.3 million shares traded.

[INOVIQ](#)

Inoviq says the Madison, Wisconsin-based Promega Corporation will market, distribute and sell its Exo-net pan-exosome capture products for exosome research.

Last year, Inoviq said it had a three-year agreement with Promega to sell its Exo-net technology with Promega's nucleic acid purification products (BD: Jul 6, 2023).

Today, the company said the supply and distribution agreement was an extension to its previous agreement with Promega, and included the rights to sell its products in all territories, with an initial term of three years.

Inoviq said its Exo-net system was a "fast, efficient and scalable" exosome isolation technology for biomarker discovery and diagnostics development.

Inoviq chair David Williams said the partnership was a "significant building block for commercializing our exosome technology platform and validates our focus on developing next generation exosome diagnostics and therapeutics".

"Exo-net's precision and efficiency, combined with Promega's leading RNA extraction technologies, established reputation and global reach should drive transformative exosome research," Mr Williams said.

"This should yield development of exosome diagnostics from bench-to-clinic," Mr Williams said.

Inoviq was up seven cents or 12.1 percent to 65 cents.

[ACTINOGEN MEDICAL](#)

Actinogen says it has treated the first of 220-patients in its randomized, phase IIb trial of Xanamem for mild-to-moderate Alzheimer's disease.

In December, Actinogen said it opened the first site for the phase IIb trial of 10mg doses of Xanamem for Alzheimer's disease, with results from the first 100 patients expected by July 2025 (BD: Dec 20, 2023).

Today, the company said the trial of Xanamem for a 36-week treatment period had begun at 13 Australian sites, would "subsequently expand to the US" and that it expected final results by July 2026.

Actinogen chief executive officer Dr Steven Gourlay said the trial was "designed to confirm that Xanamem is a safe and effective new treatment for Alzheimer's disease and represents a major opportunity for patients and the company".

"The clear priority for the next 18 months is to deliver high quality results from our on-going phase II clinical trials in depression and Alzheimer's disease, the first of which will report results [by October 2024]".

Actinogen was up 0.2 cents or 6.45 percent to 3.3 cents with 26.3 million shares traded.

[ONCOSIL MEDICAL](#)

Friday's edition wrongly implied Oncosil had treated the first patient in its radiation with chemotherapy Tripp-FFX pancreatic cancer trial, when in fact it was the first UK patient. The Oncosil ASX announcement and the Biotech Daily article referred to the 80-patient study of "targeted intra-tumoural placement of phosphorous-32 with Folfirnox (folinic acid, fluorouracil, irinotecan and oxaliplatin), as the Tripp-FXX study, when in fact it is the Tripp FFX study.

The error was made by the Friday sub-editor, who has been seconded to Cambodia's Siem Reap Daily Express & Guardian to learn meticulous accuracy.

Oncosil was up 0.1 cents or 16.7 percent to 0.7 cents with 7.45 million shares traded..

IMUGENE

Imugene says it has expanded its phase I trial of Vaxinia for metastatic advanced solid tumors to include 10 bile tract cancer patients, following positive results.

Last year, the company said it had dosed the first Vaxinia and pembrolizumab combination patients; and later, said it had 'early positive signals' from 34 patients treated with either monotherapy or combination therapy and had US Food and Drug Administration fast track status for bile duct cancer (BD: Mar 3, Nov 6, Nov 28, 2023).

Today, Imugene said it had completed dosing the fifth, high dose cohort of the trial's intra-tumoral, monotherapy arm, which included patients with thymic carcinoma, triple negative breast cancer and cholangiocarcinoma, with interim results showing "positive responses in gastrointestinal cancers, particularly in cholangiocarcinoma".

The company said cholangiocarcinoma was a "rare disease in which malignant cancer cells form in the bile ducts ... [that was] difficult to treat and responds poorly to immunotherapy drugs".

Imugene said one cholangio-carcinoma patient treated with a mid-dose of Vaxinia who had failed three prior lines of therapy achieved a complete response, or the disappearance of "all signs of cancer in response to treatment" and a second patient achieved stable disease for "more than four months".

The company said the final intra-venous monotherapy arm cohort, the second intra-tumoral combination cohort and third and final intra-venous combination cohort were ongoing and that there were "no safety signals identified to date".

Imugene fell 0.1 cents or 1.1 percent to 9.1 cents with 27.9 million shares traded.

OSTEOPORE

Osteopore has told the ASX it became aware on March 27, 2024 it would be unable to provide the necessary information to its auditors and file its annual report on time.

The ASX said that on March 13, 2024 Osteopore announced a \$3 million rights issue at 2.9 cents a share, on March 27, 2024 it said had secured market approval in Singapore and Vietnam; and later, said it had lost its ability to sell its Axopore products in Singapore, which was estimated to impact revenues.

The ASX said that on March 27, 2024 the company requested a suspension due to a delay in filing its annual report and noted its share price rose 798.8 percent from a low of 8.4 cents to a high of 75.5 cents on that day, as well as a "significant increase" in shares traded.

The ASX asked Osteopore when it became aware it would not be able to file its annual report by the due date of March 28, 2024, and whether it believed any of the information was material.

Osteopore told the ASX that it was told by its auditors they required "a number of outstanding items ... to complete the annual report" on March 25, but that it believed "it could provide the outstanding items to the auditor in sufficient time".

The company said it held a board meeting on March 27, 2024 and "formed the view that the provision of the outstanding items ... would be insufficient time to allow for the annual report to be lodged with ASX by the due date of March 28, 2024".

Osteopore said it requested a voluntary suspension on that date and said that it believed the information raised by the ASX to be material.

Osteopore was in a suspension and last traded at 30 cents.

ORTHOCELL

Orthocell says it has received \$3,051,483 from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program.

Orthocell said the incentive related to research and development expenditure for the year to June 30, 2023.

The company said it was "well-funded for its current global market expansion strategy and beyond the pivotal US product registration for Remplir expected [by April 2025]".

Orthocell was up half a cent or 1.3 percent to 38.5 cents.

ZELIRA THERAPEUTICS

Zelira says it has received \$919,000 from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program.

Zelira did not state for what period the incentive was related to but did say the funds would be used for working capital and progressing its ongoing clinical and product development.

Zelira was up two cents or 2.9 percent to 71 cents.

RADIOPHARM THERANOSTICS

Radiopharm says its extraordinary general meeting passed all eight resolutions but with up-to 11.81 percent opposition to the issue of stock to Lind Partners.

In February, Radiopharm said it had an up-to \$12.5 million draw-down equity facility with New York's Lind Partners (BD: Feb 6, 2024).

Today, the company said the resolution to approve the issue of monthly tranche shares to Lind was opposed by 18,784,049 votes (11.81%), with 140,237,444 votes (88.19%) in favor.

Radiopharm said the ratification of the issue of Lind shares, Lind options, Lind subscription shares, the issue of the first tranche of Lind shares as well as the issue of advisor options and placement shares all had up-to 10.83 percent dissent, with the ratification of shares to Pharma15 approved with 1.40 percent opposition.

According to its most recent notice, Radiopharm had 445,128,955 shares on issue, meaning that the 18,784,049 shares against the issue of monthly shares to Lind amounted to about 4.2 percent of the company, not sufficient to call extraordinary general meetings.

Radiopharm fell 0.1 cents or 2.1 percent to 4.6 cents.

MICRO-X

Micro-X has requested a trading halt pending an announcement "in respect of a material capital raising".

Trading will resume on April 17, 2024, or on an earlier announcement.

Micro-X last traded at 11.5 cents.

NEUROTECH INTERNATIONAL

Neurotech has requested a trading halt pending the release of phase II/III autism trial results and phase I/II Rett syndrome trial results as well as a capital raising.

Trading will resume on April 17, 2024, or on an earlier announcement.

Neurotech last traded at 10.5 cents.

CLARITY PHARMACEUTICALS

Clarity director Dr Chris Roberts says his 17,911,280 share-holding in the company has been diluted from 6.99 percent to 5.85 percent due to a capital raise.

The Sydney-based Dr Roberts said the shares were held with Cabbit Pty Ltd and Robwill Trust and that the parties were diluted by the issue of shares on April 8, 2024.

In March, Clarity said it had raised \$110 million at \$2.55 a share in a \$101 million placement and a \$9 million institutional rights offer, with an \$11 million retail offer closing on April 19, 2024, to follow (BD: Mar 28, 2024).

Clarity fell five cents or 1.85 percent to \$2.65 with 567,084 shares traded.

CLARITY PHARMACEUTICALS

Clarity executive chair Dr Alan Taylor says his 14,066,660 share-holding in the company has been diluted below five percent following a capital raise (see above).

According to its most recent filing, Clarity had 306,557,497 shares on issue, meaning that the Sydney-based Dr Taylor's 14,066,660 shareholding amounts to about 4.6 percent of the company (see above).

COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

The CSIRO says it has appointed Kirsten Rose as its deputy chief executive, effective from May 20, 2024.

The Organisation said Ms Rose would help lead its strategic direction, as well as focus on how the CSIRO could engage and collaborate with innovative companies and organizations, as well as help drive "simplification and sustainability".

The CSIRO said Ms Rose had been its executive director of future industries since 2020, leading a portfolio that included research in agriculture and food, human and animal health, biosecurity and manufacturing, as well as working with teams to deliver national scientific infrastructure and science and innovation-based services.

The Organisation said that, prior to joining the CSIRO, Ms Rose was the head of innovation and sustainable operations at BHP.

CLINUVEL PHARMACEUTICALS

Clinuvel says chief financial officer and company secretary Darren Keamy will resign on June 30, 2024, with Peter Vaughan appointed chief financial officer from April 16, 2024.

Clinuvel said Mr Vaughan most recently worked for Toys 'R' Us and held chief financial officer and company secretary positions at Titomic, Immuron, Amaero and Respiro.

Clinuvel said Mr Vaughan held a Bachelor of Business from Swinburne University of Technology and a Master of Business Administration from the Melbourne Business School.

The company said it would make an announcement regarding its company secretary role "in due course".

Clinuvel chief executive officer Dr Philippe Wolgen said Mr Keamy had been chief financial officer since 2005 and had helped the company "become one of the few profitable pharmaceuticals launching new molecular entities in the southern hemisphere".

"Mr Keamy leaves the company in a superior financial position," Dr Wolgen said.

"On behalf of the board and staff, I wish him well in his future endeavours as he hands over to Mr Vaughan," Dr Wolgen said.

Clinuvel was up 10 cents or 0.7 percent to \$15.20 with 86,610 shares traded.

DORSAVI

Dorsavi says non-executive director Caroline Elliot has resigned, effective from today, with the board to review potential replacements “over the coming months”.

Dorsavi said Ms Elliot was appointed a director in November 2017.

Dorsavi acting chair Dr Michael Panaccio said the company was “extremely grateful for Ms Elliott’s contribution to the company over many years”.

“We would like to thank Caroline and wish her the very best for her future endeavors,” Dr Panaccio said.

Dorsavi was unchanged at 1.4 cents.