



Biotech Daily

Thursday May 2, 2024

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: CLARITY UP 9%; SYNTARA DOWN 12%**
- * **FEDERAL GOVERNMENT: \$1.9b FOR CLINICAL TRIALS, RESEARCH**
- * **ONCOSIL RIGHTS RAISE \$5.3m; TOTAL \$6.8m**
- * **TRIVARX 'COMMITMENTS' FOR \$2.5m PLACEMENT**
- * **MTP CONNECT APPOINTED SME SUPPORT PROGRAM PARTNER**
- * **IMMUTEP EFTI, RADIOTHERAPY, KEYTRUDA SARCOMA RESPONSES**
- * **BLINKLAB, TURNING POINTE PARTNER FOR AUTISM STUDY**
- * **GREGORY GEORGE, G TO THE FOURTH TAKE 15% OF MESOBLAST**
- * **FIRSTCAPE TAKES VOLPARA 15%, PACIFIC EDGE 14%, AROA 7%**
- * **MALCOLM MCCUSKER DILUTED BELOW 5% OF PYC**
- * **BIO-MELBOURNE TO HOST 'EUROPEAN MARKET SUCCESS' SEMINAR**
- * **CHIMERIC APPOINTS DR REBECCA MCQUALTER COO, ON \$300k**
- * **TIM TIAN REPLACES MELODIOL CFO CHRIS GRUNDY**

MARKET REPORT

The Australian stock market was up 0.23 percent on Thursday May 2, 2024, with the ASX200 up 17.1 points to 7,587.0 points. Seventeen of the Biotech Daily Top 40 stocks were up, 12 were down, nine traded unchanged and two were untraded.

Clarity was the best, up 26 cents or 8.6 percent to \$3.27, with 2.4 million shares traded. Alcidion climbed 7.7 percent; Percheron was up 5.5 percent; Cynata and Dimerix improved more than four percent; Avita and Nova Eye were up more than three percent; Curvebeam, Cyclopharm and Pro Medicus rose more than two percent; Imugene, Orthocell and Proteomics were up more than one percent; with CSL, Genetic Signatures, Nanosonics, Neuren, Resmed and Telix up by less than one percent.

Syntara led the falls, down 0.2 cents or 11.8 percent to 1.5 cents, with 1.9 million shares traded. Resonance lost 6.1 percent; 4D Medical, Micro-X and Prescient fell four percent or more; Paradigm was down 3.5 percent; Medical Developments and Mesoblast shed more than two percent; Clinuvel, Next Science, Opthea and SDI were down more than one percent; with Cochlear down by 0.3 percent.

FEDERAL GOVERNMENT, AUSBIOTECH

The Federal Government says it will invest \$1.9 billion in medical research and clinical trials, through the 'Health Research for a Future Made in Australia'.

A media release from the Federal Minister for Health Mark Butler said \$1.4 billion would come from the Medical Research Future Fund, to fund a 10-year low survival program, a 10-year reducing health inequities initiative, continue existing programs and further research on women's health, chronic pain and alcohol and drug treatment.

The Federal Government said \$411 million would support 229 researchers through National Health and Medical Research Council, \$62 million for 26 clinical trials through the MRFF and \$18.8 million for the National One Stop Shop for trials and health research.

The Government said the National One Stop Shop trials network would give Australians "early access to potential lifesaving and life changing treatments, by streamlining the process to conduct a clinical trial via a single national platform and set of regulations".

The media release said the clinical trials regulatory framework was fragmented and differed from state to state "increasing the regulatory burden for research organizations, hampering interstate collaboration, and leading to postcode lottery for patients".

The Government said the National One Stop Shop would "harmonize and nationalize the administration and regulation of health and medical research, including through establishing an easy-to-use website which will help patients, researchers and industry find, conduct and participate in clinical trials and research".

Separately, Ausbiotech said it welcomed the Federal Government's \$18.8 million investment for the National One Stop Shop which it said would be a "single, harmonized, end-to-end process across the different jurisdictions".

Ausbiotech said it had advocated for a single, end-to-end process across different state jurisdictions since the Federal Government opened a Clinical Trials Action Group in 2009.

The industry organization said the Government's investment in the National One Stop Shop would "foster innovation, create jobs, and reinforce Australia's position as a global leader in research and development".

Mr Butler said the Australian health and medical research sector was "ranked seventh in the world and the new national strategy will help our researchers continue to outperform".

"Better alignment and coordination of the MRFF and NHMRC funds will achieve the best of both and strengthen Australia's world-leading research capability to change and improve the health and lives of Australians," Mr Butler said.

"The National One Stop Shop will remove needless red tape and help end the postcode lottery in access to clinical trials, to make it easier for Australian researchers and patients to conduct and take part in potentially life-changing health research," Mr Butler said.

ONCOSIL

Oncosil says its one-for-two entitlement offer has raised \$5.3 million at 0.5 cents a share, taking the total raised with the placement to \$6.8 million.

In March, Oncosil said it had commitments for a \$1.48 million placement and hoped to raise up-to \$5.65 million in a rights offer, underwritten to \$2 million by joint lead managers Forrest Capital and McFarlane Cameron (BD: Mar 20, Mar 21, 2024).

Today, the company said the rights offer raised \$3.3 million and it received \$300,000 in the shortfall offer, with a further \$1.7 million to be received under the shortfall offer.

Oncosil said investors would receive one long and two short date options for every two shares bought, exercisable at 3.0 cents and 0.9 cents by April 30, 2027 and June 30, 2025, respectively.

Oncosil fell 0.1 cents or 20 percent to 0.4 cents with 8.5 million shares traded.

TRIVARX (FORMERLY MEDIBIO)

Trivarx says it has “firm commitments” to raise \$2.5 million at 2.5 cents a share in a placement to fund its phase II sleep signal study of MEB-001 depression algorithm. Trivarx said the placement price was a 0.79 percent discount to the 15-day volume weighted average price.

The company said the funds would be used to complete its phase II sleep study and for “US regulatory approval initiatives for its ... MEB-001 algorithm” to diagnose major depressive episodes.

Trivarx said it would seek shareholder approval to issue S3 Consortium Pty Ltd \$350,000 in shares at the placement price for investor relations services for the next two years.

The company said JP Equity Partners was lead manager to the placement and would receive 2,500,000 options in fees, exercisable at five cents each within three years from their issue date, subject to shareholder approval.

Trivarx was up 0.3 cents or 11.5 percent to 2.9 cents with 24.2 million shares traded.

FEDERAL GOVERNMENT MTP CONNECT

The Federal Government says it has opened its Industry for Growth Program up to \$5 million each grant applications for small and medium businesses.

Last year, the Government said the \$392 million program would help start-ups and small-to-medium businesses (SMEs) commercialize, with advisory services and matched grant funding from \$50,000 to \$5,000,000 (BD: Nov 27, 2024).

Today, a media release from the Minister for Industry and Science Ed Husic said the mentoring and advice portion of the program had supported more than 340 businesses since opening in November last year, and the grants would provide “targeted support for SMEs across the National Research Fund’s seven priority areas”.

The Government said it had appointed MTP Connect as one of four industry partner organization applicants, which would receive a combined \$6.9 million to provide advice to program participants.

The Federal Government said the other recipients of the industry partner organization included Advanced Robotics for Manufacturing Hub Ltd, Food and Agribusiness Network Ltd and Hydrogen Mobility Australia Ltd.

Separately, MTP Connect chief executive officer Stuart Dignam welcomed the announcement and said MTP Connect looked forward to delivering “more of our sought-after services and advisory support for start-ups and SMEs”.

“SME growth will be the focus of our Industry Partner Organisation work, supporting small to medium enterprises to build manufacturing capability, improve commercial outcomes and grow into larger companies,” Mr Dignam said.

“Across all our initiatives, MTP Connect has so far contributed to \$1.7 billion flowing into Australia’s medical products sector and we’re delighted our impact and deep capabilities have been recognized,” Mr Dignam said.

“Our services will complement and add value to participants of the broader Industry Growth Program and build a pipeline of opportunities for National Reconstruction Fund investment,” Mr Dignam said.

“Supporting life science companies to grow and scale here in Australia encourages them to remain here longer, building the ecosystem for future growth - securing jobs, investment and increased onshore economic activity,” Mr Dignam said.

More information on eligibility for grants under the Industry Growth Program is available at: <http://www.industry.gov.au/IGP>.

IMMUTEP

Immutep says four of six soft tissue sarcoma patients in an up-to 40-patient phase II trial of eftilagimod alpha, or efti, with standard-of-care have “near-complete responses”. Last year, Immutep said it would provide efti, previously called IMP321, to the Warsaw, Poland-based Maria Skłodowska-Curie National Research Institute of Oncology to conduct an up-to 40-patient, open-label phase II trial in combination with radiotherapy and pembrolizumab, or Keytruda, for soft tissue sarcoma (BD: Apr 17, 2023).

Today, the company said the trial showed no safety issues and efti was well-tolerated in the first six patients who had completed the 10 weeks of treatment followed by surgery two to three weeks later.

Immutep said initial efficacy data was “very encouraging with four of six patients having near-complete responses”.

The company said near-complete responses were “rarely seen in soft tissue sarcoma patients with standard therapeutic approaches including radiotherapy”.

Immutep said the trial had enrolled 14 patients, with additional clinical data planned to be presented at a medical conference by the end of this year.

Immutep chief scientific officer Prof Frédéric Triebel said “the ability to evaluate tumor specimens is helping elucidate the significant anti-cancer immune response efti drives through its direct maturation and activation of antigen-presenting cells”.

“If the positive trend of strong pathological responses continues in this rare orphan disease, we will pursue all available avenues to bring this innovative therapy to soft tissue sarcoma patients in need of new, effective therapies in an expeditious manner,” Prof Triebel said.

Immutep was unchanged at 42 cents with 3.4 million shares traded.

BLINKLAB

Blinklab says it will conduct an up-to 200-child study of its artificial intelligence-based smartphone autism diagnostic with Chicago’s Turning Pointe Autism Foundation.

Blinklab said the study would enroll 100 patients with a previous autism diagnosis and 100 children without a previous diagnosis.

The company said participants would undergo 15-minute testing with its platform, which measured postural, head, facial and vocal responses to stimuli as well as an acoustic startle response, pre-pulse inhibition and both long and short-term habituation.

Blinklab said the data collected would be used to finalize data collection, processing algorithms and machine learning models ahead of a US Food and Drug registrational study, which was expected to begin by 2025.

Blinklab said Turning Pointe was an organization intended to “meet the specific and unique needs of students learning with autism” and offered individuals with autism aged five-to-22 years programs to support their growth, development, and employment.

Blinklab was up 1.5 cents or 4.8 percent to 32.5 cents with 1.2 million shares traded.

MESOBLAST

Gregory George and G to the Fourth Investments say they have increased their Mesoblast holding from 150,183,635 shares (13.20%) to 166,849,364 shares (14.67%).

The Tampa, Florida-based Mr George said the shareholders included James George, Grant George, Citicorp and JP Morgan; and the shares were acquired between April 4 and 30 with the single largest purchase 10,000,000 shares for \$10,426,000 or \$1.04 a share.

Mesoblast fell three cents or 2.7 percent to \$1.07 with 26.8 million shares traded.

[VOLPARA HEALTH TECHNOLOGIES, PACIFIC EDGE, AROA BIOSURGERY](#)

Firstcape Group Ltd says following its acquisition of Harbour Asset Management it has become substantial in Volpara, Pacific Edge and Aroa.

In separate announcements made to the ASX, the Wellington, New-Zealand-based Firstcape said that it held 38,560,762 Volpara shares (15.16%); 116,356,180 Pacific Edge shares (14.34%); and 24,894,494 Aroa shares (7.23%).

Yesterday, Wellington's Jarden Securities Ltd said it had ceased its Pacific Edge shareholding after selling Harbour to Firstcape on April 30, 2024 (BD: May 1, 2024).

Volpara was unchanged at \$1.14 with 954,888 shares traded.

Pacific Edge was up half a cent or 6.25 percent to 8.5 cents.

Aroa was unchanged at 50 cents.

[PYC THERAPEUTICS](#)

Malcolm McCusker says his 227,000,000 share-holding in PYC was diluted below the five percent substantial shareholder threshold due to a share issue on April 30, 2024.

Last month, PYC said its one-for-four retail right offer raised \$13.5 million and it had "binding commitments" to place the \$21.2 million shortfall, taking the total to \$74.6 million (BD: Mar 14, Mar 18, Apr 11, 2024).

According to its most recent application, PYC had 4,666,083,409 shares on issue, meaning that the Perth-based Mr McCusker's 227,000,000 shareholding was about 4.86 percent of the company.

PYC was up 0.3 cents or 3.1 percent to 10 cents with 2.3 million shares traded.

[BIO-MELBOURNE NETWORK](#)

The Bio-Melbourne Network says it will host a seminar on "the challenges and opportunities that arise during the transition from discovery to approval" in June.

The Bio-Melbourne Network said the seminar, titled 'Biopharma Masterclass: Bridging Discovery to Clinical: A Roadmap for European Market Success' would be held with the Hannover-based Serum Life Science Europe GmbH from June 19 to 21, 2024.

The Network said Serum Life Science was a German-based regulatory consultancy and that the event would "provide participants with the knowledge and strategies necessary for successful clinical development and European regulatory approval".

The Bio-Melbourne Network said it had not finalized a venue for the event, which included a forum, masterclass and 30-minute advisory session.

For expressions of interest to register, go to: <https://bit.ly/4dk9OyN>.

[CHIMERIC THERAPEUTICS](#)

Chimeric says it has appointed Dr Rebecca McQualter as its chief operating officer, on a salary of \$300,000 a year.

Chimeric said Dr McQualter was most recently Novartis Australia head of strategic access and had previously worked at Bioverativ, Amgen and Glaxosmithkline.

According to her LinkedIn page Dr McQualter held a Bachelor of Science and a Doctor of Philosophy from Melbourne's Monash University.

Chimeric said Dr McQualter's would be entitled to a variable remuneration incentive of up-to 40 percent of her \$300,000 a year base salary, subject to milestones and she would receive 20 million options, vesting over four years.

Chimeric was up 0.2 cents or 7.4 percent to 2.9 cents with 1.5 million shares traded.

[MELODIOL GLOBAL HEALTH \(FORMERLY CRESO PHARMA\)](#)

Melodiol says financial controller Yuan (Tim) Tian has been appointed as chief financial officer, replacing Chris Grundy, effective from May 1, 2024.

Melodiol said Mr Tian had been with the company for more than three years.

Melodiol managing-director William Lay thanked “Mr Grundy for his incredible contributions to the company over the preceding years”.

Melodiol was up 0.1 cents or 33.3 percent to 0.4 cents.