

Biotech Daily

Wednesday October 9, 2024

Daily news on ASX-listed biotechnology companies

- * ASX UP, BIOTECH DOWN: UNIVERSAL BIOSENSORS UP 7%; MESOBLAST DOWN 5%
- * PROF ANDREW WILKS, DR CHRIS BURNS WIN PM'S \$250k INNOVATION PRIZE
- * CORRECTION: CHIMERIC
- * HMRI WINS \$2m NEWCASTLE PERMANENT BANK DONATION
- * PACIFIC EDGE H1 TEST PROCESSING DOWN 22% TO 14k
- * RECCE DOSES 15 OF 30 PHASE II R327 BACTERIAL INFECTION PATIENTS
- * PHARMAUST RECEIVES \$887k FEDERAL R&D TAX INCENTIVE
- * GENETIC TECHNOLOGIES \$1.8m FEDERAL RDTI REPAYS \$653k LOAN
- * PROTEOMICS 2.85m M-D, DIRECTOR OPTIONS AGM
- * AROVELLA: 1.7m M-D OPTIONS; DIRECTOR OPTIONS IN LIEU OF FEES AGM
- * ADHERIUM POTENTIAL 2nd STRIKE, BOARD SPILL AGM
- * ARGENT: 300k MERCER NOTES CONVERSION PRICE DROP FROM \$10 TO 30c
- * REGAL FUNDS REDUCES TO 6% OF CARDIEX
- * DUTCH INK TAKES 9% OF NEUROTECH
- * ECHO IQ APPOINTS DUSTIN HAINES US CEO ON \$593k PA
- * ALLEGRA DR NICHOLAS HARTNELL TAKES 90%, COMPULSORY ACQUISITION

MARKET REPORT

The Australian stock market was up 0.13 percent on Wednesday October 9, 2024, with the ASX200 up 10.5 points to 8,187.4 points. Fourteen of the Biotech Daily Top 40 companies were up, 21 fell and five traded unchanged. All three Big Caps were up.

Universal Biosensors was the best, up one cent or 6.9 percent to 15.5 cents, with 119,828 traded; followed by Orthocell, up 3.5 cents or 6.8 percent to 55 cents, with 1.7 million shares traded. Pro Medicus improved four percent; Dimerix and Starpharma climbed more than three percent; Micro-X and Resmed rose two percent or more; Alcidion, Compumedics, Immutep and Percheron were up by one percent or more; with 4D Medical, Cochlear, CSL, Nanosonics, Proteomics and Telix up by less than one percent.

Mesoblast led the falls, down 7.5 cents or 5.1 percent to \$1.39, with 7.5 million shares traded. Atomo fell 4.8 percent; Actinogen, Amplia, Clarity, Curvebeam, Cynata and Neuren lost three percent or more; Avita, Cyclopharm, Emvision, Imugene, Nova Eye, Prescient and Syntara shed two percent or more; Impedimed, Opthea, Polynovo and Resonance lost more than one percent; with Aroa and SDI down by less than one percent.

PRIME MINISTER'S SCIENCE PRIZES

Prof Andrew Wilks and Dr Chris Burns have won the \$250,000 2024 Prime Minister's Prize for Innovation for inventing and commercializing momelotinib for myelofibrosis. Last year, Prof Andrew Wilks said that after 20 years of development, the US Food and Drug Administration has approved Ojjaara (previously Cytopia's momelotinib or CYT387) for the blood cancer myelofibrosis (BD: Sep 18, 2023).

Prof Wilks and Dr Burns told Biotech Daily at that time that Cytopia had been sold to Toronto's YM Biosciences in 2009 for \$14 million, which then raised \$US46 million for CYT387; in 2012, Gilead Sciences said it would acquire YM Biosciences for \$US510 million; it was widely reported that in 2018, Gilead sold the drug to Vancouver's Sierra Oncology for \$US3 million; and last year Sierra sold CYT387 to Glaxosmithkline for \$US1.9 billion (\$A2.9 billion) (BD: Oct 6, 2009; Mar 18, 2011; Dec 13, 2012). Prof Wilks said that CYT387 or momelotinib "was the only asset of Sierra Oncology which was ultimately acquired by [Glaxosmithkline] in 2022 for US\$1.9 billion in an all-cash deal, making it the highest acquisition amount paid for a drug invented in Australia". A Federal Government media release said that Australia's Prime Minister Anthony Albanese the Federal Minister for Industry and Science Ed Husic announced the recipients at a presentation at Canberra's Parliament House.

The media release said that Prof Matthew Bailes won the \$250,000 Prime Minister's Prize for Science "for his world-first discovery of fast radio bursts" helping understand how much matter exists in the universe and recognizing his "leadership of Australian astronomy". The Government said that Prof Britta Regli-von Ungern-Sternberg won the \$50,000 Frank Fenner Prize for Life Scientist of the Year "for her life-changing research into reducing risks associated with anaesthesia for children ... making surgery and recovery safer". The media release said Prof Tianyi Ma won the \$50,000 Malcolm McIntosh Prize for Physical Scientist of the Year "for his groundbreaking work in renewable energy" [which] could support Australia in its clean energy transition and path to net zero". The Government said Daniel Edwards won the \$250,000 Prime Minister's Prize for Excellence in Science Teaching in Primary Schools and Alice Leung won the \$250,000 Prime Minister's Prize for Excellence in Science Teaching in Secondary Schools. The media release said that Dr Andrew Horsley won the \$50,000 Prize for New Innovators

prize for his "innovations towards making quantum computing an everyday technology". The Government said the prizes for primary and secondary science teaching were increased from \$50,000 each to \$250,000 each, for "teachers who have made significant contributions to science, technology, engineering or mathematics education".

CORRECTION: CHIMERIC THERAPEUTICS

Monday's article on a Chimeric patient's complete response to CHM0201 with standard-of-care vactosertib for acute myeloid leukaemia included an incorrect catch-up paragraph. The article referred to a separate 20-patient Chimeric trial at Houston's University of Texas MD (Monroe Dunaway) Anderson Cancer Center of CHM0201 with azacitidine and venetoclax for acute myeloid leukaemia patients who were ineligible for intensive chemotherapy or allogeneic stem cell transplant (BD: Sep 13, 2023).

Chimeric chief operating officer Dr Rebecca McQualter has told Biotech Daily that the 12-patient trial combining CHM0201 with standard-of-care vactosertib for acute myeloid leukaemia was being conducted at the Cleveland Ohio-based Case Comprehensive Cancer Center and led by Dr Eva Selfridge.

The error was made by the Monday sub-editor who has been dismissed. Chimeric was in a suspension and last traded at 1.4 cents.

HUNTER MEDICAL RESEARCH INSTITUTE

The Hunter Medical Research Institute (HMRI) says the New South Wales' Newcastle Permanent bank has donated \$2 million for its research.

The HMRI said the funds would be used for an 'Innovation Accelerator' to progress research concepts and the 'Newcastle Permanent Emerging Innovator Award' that would recognize promising researchers at the University of Newcastle and the Hunter New England Local Health District.

The Institute said Newcastle Permanent was "one of Australia's largest customer-owned banks" and was part of Newcastle Greater Mutual (NGM) Group Ltd.

The HMRI said the partnership would establish "a pre-investment program designed to support emerging researchers in advancing their innovative ideas from conception to market readiness".

The Institute said the program would provide mentoring and strategic guidance and aimed "to bridge the critical gap that often exists between groundbreaking research and successful commercialization".

HMRI chief executive officer Prof Frances Kay-Lambkin said that the collaboration would "drive novel health solutions by combining our ecosystem's world-class research with Newcastle Permanent's unwavering commitment to community wellbeing".

"A key focus is supporting emerging researchers in the Hunter New England region as they work to tackle the diseases affecting our families, friends and communities," Prof Kay-Lambkin said.

"The Newcastle Permanent was one of three founding partners in the establishment of HMRI over 26 years ago, transforming our local health and medical research effort at the time," Prof Kay-Lambkin said.

PACIFIC EDGE

Pacific Edge says it sales of its Cxbladder urine test for bladder cancer for the six months to September 30, 2024 were down 22.0 percent to 14,233 tests.

Last year, Pacific Edge said revenue for the six months to September 30, 2023 was up 50.4 percent to \$NZ13,095,000 (\$A11,920,002) with the three months to June 30, 2023 a record quarter (BD: Nov 23, 2023).

Today, the company said that it processed 7,045 Cxbladder tests in the three months to September 30, 2024, down 2.0 percent from 7,188 tests in the prior period.

Pacific Edge said the recent Centers for Medicare and Medicaid Services decision to extend Novitas' deliberations to finalize or withdraw changes that would limit reimbursement for its Cxbladder cancer tests in the US "added to the challenges faced by the sales team".

Last year, the company said Novitas did not consider its tests "medically reasonable and necessary", the threshold for US medical coverage (BD: Jul 28, 29, 2023).

Today, Pacific Edge said processed tests for the six months to September 30, 2024 fell 22.0 percent from 18,240 tests to 14,233, during which it undertook "a reorganization to reduce the size of its sales team to preserve cash to weather the Medicare uncertainty".

The company said that its US laboratories processed 5,682 tests for the three months to September 30, 2024, down 3.8 percent, while tests processed in Asia Pacific were up 6.2 percent from 1,283 tests in the previous three months to 1,363 tests.

Pacific Edge said that "continuing strong demand from our US customer Kaiser Permanente, the sustained benefits of our sales force efficiency gains and a lift in volume in the Asia Pacific region diluted the impact of these factors".

Pacific Edge was untraded at 12.0 cents.

RECCE PHARMACEUTICALS

Recce says it has dosed 15 of 30 patients in a phase II trial of its R327 topical gel for bacterial skin infections and skin structure infections, including diabetic foot infections. In June, Recce said it had ethics approval for a 30-patient, open-label, phase II trial of its R327 topical gel for "all bacterial skin infections" (BD: Jun 24, 2024).

At the time, the company said the trial would study the bio-availability of single and multiple-doses of R327 as a treatment for a "broad range" of acute bacterial skin and skin structure infections, including diabetic foot infections, necrotizing fasciitis and post-operative wound infections, as well as clinical efficacy and toxicity.

Today, Recce said R327 was shown "to be safe and well-tolerated across human subjects, with indications of promising antibacterial responses observed in patients". The company said the initial data was a "significant opportunity to expand the application

of R327 [topical gel] formulation".

Recce said it had added the Australian Clinical Research Network in Sydney and Melbourne as two additional clinical sites, as well as the lead site Barwon Health.

The company said it was on track to complete enrolment "this calendar year".

Recce managing-director James Graham said the company was "thrilled to pass the halfway point of this pivotal phase II clinical study for the unmet clinical need of topical skin infections".

"Indications of promising antibacterial effect is a significant achievement, with patient recruitment to be completed within the year," Mr Graham said.

"The market for [acute bacterial skin and skin structure infections] is expanding as a result of an increase in the frequency of bacterial skin infections, particularly those brought on by drug-resistant strains," Mr Graham said. "The acute lack of effective broad-spectrum antimicrobials contributes significantly to this challenge."

Recce was up 1.5 cents or 2.8 percent to 55 cents.

PHARMAUST

Pharmaust says it has received \$887,129 from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program.

Pharmaust said the incentive related to expenditure for the year to June 30, 2024.

The company said it had submitted an advance overseas finding application to claim for eligible overseas research and development for the year to June 30, 2024, which it expected to be about \$655,274.

Pharmaust was up one cent or 5.1 percent to 20.5 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says it has repaid \$652,743 to Radium Capital following the receipt of its \$1.84 million research and development tax incentive.

Earlier this year, Genetic Technologies said it had taken a Radium Capital loan of \$600,000 at 1.33 percent monthly interest against 80 percent of its expected research and development tax incentive (BD: Mar 26, 2024).

Last week, the company said that it had received \$1.84 million from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program (BD: Oct 3, 2024).

Today, the company said the net amount received by the company following the repayment of the Radium Capital loan was about \$1.19 million.

Genetic Technologies was unchanged at four cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says its annual general meeting will vote to issue managing-director Dr Richard Lipscombe 2,600,000 options and director Dr James Williams 250,000 options. Proteomics said investors would vote to issue Dr Lipscombe 1,000,000 options exercisable at \$1.50, 800,000 exercisable at \$2.50 and 800,000 exercisable at \$3.50. The company said investors would vote to issue Dr Williams 250,000 options exercisable at \$1.50 each within three years from grant.

Proteomics said the meeting would vote to adopt the remuneration report, re-elect Dr Williams and Neville Gardiner as directors, the prior issue of shares, increase the maximum number of incentive options issuable from 6,110,000 options to 22,690,407 options for a three-year period and amend its constitution.

The meeting will be held at Harry Perkins Institute, QEII Medical Centre, QQ Block, 6 Verdun Street, Perth on November 8, 2024 at 9.30am (AWST).

Proteomics was up half a cent or 0.6 percent to 80.5 cents with 2.2 million shares traded.

AROVELLA THERAPEUTICS

Arovella says its annual general meeting will vote to issue 1,658,483 options to managing-director Dr Michael Baker and director's options in lieu of fees.

Arovella said Dr Baker's options were part of his long-term incentive for the year to June 30, 2024, would vest in three equal tranches yearly and were exercisable at 21.75 cents each, or 150 percent of its share price at July 1, 2024, by June 30, 2028.

The company said shareholders would vote to issue options to non-executive directors Gary Phillips, Dr Debora Barton and Dr Elizabeth Stoner as well as chair Dr Thomas Duthy in lieu of a proportion of their directors' fees for the year to June 30, 2024. Arovella said Mr Phillips' remuneration would be split as \$44,600 in cash and \$40,000 in options, with Dr Barton and Dr Stoner to both receive \$US40,000 (\$A59,443) in cash and \$40,000 in options and Dr Duthy to be paid \$100,350 in cash and \$70,000 in options.

The company said the director options would be exercisable at 150 percent of the 30-day volume weighted average price to the issue date within 60 months from issue.

Arovella said investors would vote on the remuneration report, elect Dr Stoner and Dr Barton as directors, ratify the prior issue of shares and approve the placement capacity. The meeting will be held at Thomson Geer, Level 23, Rialto South Tower, 525 Collins Street, Melbourne on November 15, 2024 at 11am (AEDT).

Arovella was up one cent or 6.45 percent to 16.5 cents with 1.3 million shares traded.

ADHERIUM

Adherium says its annual general meeting will vote on the remuneration report and, potentially, a second-strike board spill

Last year, Adherium said its annual general meeting voted a remuneration report first strike with 528,901,384 votes (27.72%) in opposition (BD: Dec 1, 2023)

Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive meetings is required to vote on a board spill.

The company said the meeting would vote to re-elect director George Baran, amend the constitution and approve the additional 10 percent placement capacity.

The meeting will be held online and in person at K&L Gates, Level 25, Rialto South Tower, 525 Collins Street, Melbourne, on November 15, 2024 at 11am (AEDT). Adherium was untraded at 1.4 cents.

ARGENT BIOPHARMA (FORMERLY MGC PHARMACEUTICALS)

Argent says the minimum conversion price for 300,000 of its 1,600,000 convertible notes with Mercer Street Global has been reduced from \$10 to 30 cents.

In 2020, the-then MGC Pharmaceuticals said that it had an up to \$15 million draw-down facility with the New York-based Mercer Street Global Opportunity Fund LLC, with \$2.25 million to be received upfront (BD: Sep 10, 2020).

Argent was unchanged at 55 cents.

CARDIEX

The Sydney-based Regal Funds says it has reduced its substantial shareholding in Cardiex from 21,417,413 shares (7.28%) to 17,766,683 shares (6.04 percent). Regal Funds said that it sold shares between April 19 and October 4, 2024, with the single largest sale 736,107 shares on October 4 for \$41,075, or 5.6 cents a share. Cardiex was up 0.2 cents or 3.6 percent to 5.7 cents.

NEUROTECH INTERNATIONAL

The Perth-based Dutch Ink Pty Ltd says it has become a substantial shareholder in Neurotech with 94,341,233 shares, or 9.11 percent.

Dutch Ink said that it bought shares between August 1, 2020 and October 4, 2024, but failed to disclose the amount and cost as required under the Corporations Act 2001. Neurotech was up 0.15 cents or three percent to 5.15 cents with 1.2 million shares traded.

ECHOIQ

Echo IQ says it has appointed the US-based Dustin Haines as its chief executive officer, effective from January 10, 2025, to be paid \$US400,000 (\$A593,188) a year. Echo IQ said Mr Haines was based in the US and would focus on strategy including US commercialization and obtaining market access and technology reimbursement. Yesterday, the company said that it had US Food and Drug Administration 510(k) clearance to market and sell the artificial intelligence-based Echosolv AS for detecting aortic stenosis (AS), and the first step of commercialization was the "appointment of a suitably credentialed chief executive officer based in the US" (BD: Oct 8, 2024). Today, Echo IQ said Mr Haines had 25 years of experience including as head of Gilead Sciences Asia, Middle East, Turkey and Russia, Next Science chief commercial officer and "senior roles" at Viiv Healthcare and Glasxosmithkline.

According to his Linkedin profile, Mr Haines held a Bachelor of Arts from Pullman's Washington State University.

The company said Mr Haines would replace interim managing-director Andrew Grover, who would remain as executive chair.

Earlier this year, Echo IQ said chief executive officer Kimber Rothwell had "stepped down", with chair Andrew Grover acting as interim chief executive officer (BD: Apr 21, 2024).

Echo IQ was up seven cents or 29.2 percent to 31 cents with 61.8 million shares traded.

ALLEGRA MEDICAL TECHNOLOGIES

Allegra says director Dr Nicholas Hartnell and Allegra Innovations have acquired 90 percent of the company and will compulsory acquire all of its remaining shares. In May, Allegra said Allegra Innovations Pty Ltd, a related party of director Dr Hartnell, would pay 0.4 cents a share in a cash bid, valuing it at \$478,444 (BD: May 27, 2024). On Monday, Dr Hartnell said with Robinwood and Allegra Innovations he had increased his substantial shareholding from 107,411,776 shares (89.80%) to 108,623,456 shares (90.81%) (BD: Oct 7, 2024).

Today, Allegra said shareholders could accept the offer by October 14, 2024 at 7pm (AEDT), and if they failed to do so they would be unable to claim the consideration for their shares until the compulsory acquisition was completed.

Allegra was in a suspension and last traded at 2.9 cents.