



Biotech Daily

Wednesday October 16, 2024

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: SYNTARA UP 7.5%; ALCIDION DOWN 8%**
- * **FEDERAL \$22m FOR 14 CANCER TRIALS GROUPS**
- * **PRO MEDICUS \$32m UNNAMED AUSTRALIAN RADIOLOGY EXTENSION**
- * **AMPLIA STARTS FINAL AMP945 PANCREATIC CANCER TRIAL COHORT**
- * **ENLITIC: 'PHILIPS INCORPORATES, BAYER DISTRIBUTES ENDEX'**
- * **EBR FILES WISE CRT FOR US GOVERNMENT REIMBURSEMENT**
- * **VITALIS DEAL WITH SERVITA FOR QUEENSLAND PROJECTS**
- * **RADIOPHARM: ATOMVIE TO MANUFACTURE LU-177-BETABART**
- * **OPYL, COMMERCIAL EYES TRIALKEY DEAL**
- * **CLINUVEL AGM 2nd STRIKE; BOARD SPILL FAILS**
- * **OPTHEA 13m DIRECTOR OPTIONS AGM**
- * **NYRADA 'READY FOR NYR-BI03 TRIAL IN 2024'**
- * **PERCHERON REQUESTS 'CAPITAL RAISING' TRADING HALT**
- * **ANTEOTECH REQUESTS 'ULTRANODE COUNTERPARTY' TRADING HALT**
- * **PENGANA TAKES 7.7% OF ENLITIC**
- * **ARGENT FOUNDER, M-D ROBY ZOMER TAKES 9.9%**
- * **NANOSONICS TO LOSE DIRECTORS DR DAVID FISHER, GEOFF WILSON**
- * **BIO-MELBOURNE 'SCALING SUSTAINABLY' MASTERCLASS**

MARKET REPORT

The Australian stock market fell 0.41 percent on Wednesday October 16, 2024, with the ASX200 down 33.7 points to 8,284.7 points. Thirteen of the Biotech Daily Top 40 stocks were up, 19 fell, six traded unchanged and two were untraded. All three Big Caps fell.

Syntara was the best, up 0.3 cents or 7.5 percent to 4.3 cents, with 1.85 million shares traded. Impedimed and Prescient improved more than four percent; Actinogen, Genetic Signatures and Resonance climbed more than three percent; Paradigm rose 2.5 percent; Compumedics, Cyclopharm and Micro-X were up more than one percent; with 4D Medical, Avita and SDI up by less than one percent.

Alcidion led the falls, down 0.5 cents or 8.1 percent to 5.7 cents, with 1.7 million shares traded. Mesoblast lost 5.5 percent; Clarity, Nanosonics and Proteomics fell four percent or more; Immutep, Polynovo and Telix were down more than three percent; Aroa, Clinuvel, Cochlear, Cynata, Dimerix, Medical Developments, Neuren, Nova Eye, Orthocell and Pro Medicus shed two percent or more; Medadvisor and Opthea were down more than one percent; with CSL and Resmed down by less than one percent.

FEDERAL GOVERNMENT

The Federal Government says it has granted 14 Australian cancer trial groups \$22.19 million through its Support for Cancer Clinical Trials program.

The Federal Government said the program, part of Cancer Australia's Australian Cancer Plan, would fund multi-site, collaborative cancer clinical trial groups that might not attract commercial interest, including rare and less common cancers.

A media release from the Minister for Health and Aged Care Mark Butler said the Australian Cancer Plan aimed to promote research investment, particularly for unmet and emerging medical needs, as well as focusing on improving trial design, enhancing equitable access to trials and accelerating the translation of research into clinical practice. The Federal Government said that the clinical trials program had increased the number and value of successful grant submissions, expanded clinical trial sites and increased patient recruitment, particularly in rural and remote areas.

The Government media release said that the clinical trials program was "globally unique, designed to fund the development of clinical trial protocols and build sector capacity through core infrastructure funding".

"It fills a critical research funding gap in Australia by supporting the advancement of cancer prevention, treatment, and care programs that may not attract commercial interest from industry," the media release said.

The Government said that the program was "crucial for smaller [clinical trials groups] focused on rare and less common cancers, helping to build a strong pipeline of cancer clinical trials".

The media release said that the 14 trials groups were the Australasian Gastro-Intestinal Trials Group; Australasian Leukaemia & Lymphoma Group; Australian & New Zealand Children's Haematology Oncology Group; Australia New Zealand Gynaecological Oncology Group; Australia and New Zealand Sarcoma Association; Australian New Zealand Urogenital and Prostate Group; Breast Cancer Trials; Cooperative Trials Group for Neuro-Oncology; Cancer Symptom Trials; Melanoma and Skin Cancer Trials; Primary Care Collaborative Cancer Clinical Trials Group; Psycho-Oncology Co-operative Research Group; Thoracic Oncology Group Australasia; and Trans-Tasman Radiation Oncology Group.

Mark Butler said "the \$22.2 million investment in cancer clinical trials is a vital step toward saving lives and ensuring that all Australians, regardless of where they live, have access to the most advanced and effective treatments".

"These trials are not just about research; they are about providing hope and delivering real, life-saving outcomes for people affected by cancer," Mr Butler said, Cancer Australia chief executive officer Prof Dorothy Keefe said "by supporting these clinical trials, we are advancing critical research and ensuring that innovative treatments reach those who need them most, helping to save lives and reduce disparities in cancer care across Australia".

PRO MEDICUS

Pro Medicus says it has a minimum \$32 million, five-year contract extension with an unnamed "large Australian radiology network" for its Visage RIS imaging product.

Pro Medicus said it negotiated the extension for the Visage radiology information system (RIS) at an "increased fee".

Pro Medicus chief executive officer Dr Sam Hupert said "this contract extension cements our leadership position when it comes to RIS in the Australian market".

Pro Medicus fell \$4.53 or 2.4 percent to \$185.85 with 147,970 shares traded.

AMPLIA THERAPEUTICS

Amplia says it has restarted recruitment of the remaining 24 patients in its 50-patient phase IIa trial of narmafotinib, or AMP945, in combination for pancreatic cancer.

In August, Amplia said five of six patients had a confirmed partial response in its trial of narmafotinib, with chemotherapy for advanced pancreatic cancer, with one more response needed to continue enrolment (BD: Aug 21, 2024).

Last month, the company said that a sixth patient had shown reduced tumor size with no new lesions (BD: Sep 23, 2024).

Today, Amplia said it would begin recruiting at existing trial sites in Australia and South Korea, including Newcastle's Calvary Mater Hospital, with recruitment of this cohort expected to be completed by April 2025.

Amplia chief executive officer Dr Chris Burns said "we are very pleased to begin recruitment of the remaining 24 patients for the Accent trial".

"We plan to complete recruitment by the end of March 2025, and to increase the opportunities for patients to join the trial we have this week also opened recruitment at the Calvary Mater Hospital in Newcastle," Dr Burns said.

Amplia was unchanged at 15 cents.

ENLITIC

Enlitic says Philips Healthcare will integrate Endex into their platform for three years, and it has a three-year distribution deal with Bayer Healthcare for Endex.

Enlitic said its deal with Amsterdam's Philips through its distributor Blackford was for a limited number of sites, with the opportunity to expand, and expected the agreement to contribute between \$US100,000 (\$A149,474) to \$US380,000 (\$A568,002) each year, assuming satisfactory completion of on-site validation testing on Philip's images.

The company said Endex would "streamline radiology workflow" for the global picture archiving and communication system vendor.

Separately, Enlitic said that, once validation testing had been completed, the Leverkusen, Germany-based Bayer would integrate Endex into its radiation dose management proprietary software products, with initial rollout for up-to 50 radiology sites and potential expansion for up-to 200 sites.

The company said this was its third deal with Bayer and that it expected to receive \$US50,000 in annual revenue from the agreement.

Enlitic was up 0.9 cents or 14.1 percent to 7.3 cents.

EBR SYSTEMS

EBR says it has filed a 'new technology add-on payment application' to the US Centers for Medicare and Medicaid Services for reimbursement of its Wise wireless pacemaker.

EBR said the application followed US Food and Drug Administration breakthrough device designation for its Wise cardiac re-synchronization therapy (CRT) cardiac pacing device, meaning the product met the revised technology and clinical improvement requirements and that it was "confident in achieving the cost criterion".

The company said the application for reimbursement was "a significant milestone in EBR's commercialization strategy to achieve US reimbursement, and underpins patient access to our unique technology and accelerating adoption in the US market".

EBR said it expected FDA regulatory approval by April 2025, with Medicare coverage expected to begin by 2026.

EBR was up 1.5 cents or 1.4 percent to \$1.065.

VITALIS SOLUTIONS

Vitalis says it has a “long-term collaboration” deal with London’s Servita to work on projects related to the \$10 billion Queensland Health Capital Expansion Program. Brisbane’s Vitalis said the partnership would help it expand its reach in Australian healthcare, with Servita to provide additional capabilities and support to assist Queensland health projects, as well as wider demand in Australia.

The company said the support would be “broad” and include program and project management, a project management office, enterprise architecture, business and clinical analysis, transformation, technical delivery management and assurance, and testing-as-a-service to enable the effective and efficient provision of digital hospital information technology (IT) infrastructure.

Vitalis said Servita would open a new office in Sydney and provide hospital digital design, application procurement, integration and implementation, the establishment of digital hospital IT departments and the managed service operations of IT.

The company Servita would provide “additional capacity for the digitalization opportunities” in the healthcare sector.

Vitalis chief executive officer John Graham said the collaboration would “strengthen our depth of capabilities and extend our operational capacity to support the growing needs of digital healthcare systems in Queensland”.

“Our partnership with Servita allows us to combine our local knowledge and healthcare expertise with their global experience, creating a powerful force to lead healthcare innovation in Australia,” Mr Graham said.

Vitalis is a private company.

RADIOPHARM

Radiopharm says the Hamilton, Ontario-based Atomvie Global Radiopharma will help develop and manufacture lutetium-177-Betabart for Radiopharm Ventures.

Radiopharm said Lu-177-Betabart was a lutetium-177 conjugated radio-antibody that targeted B7-H3, an immune checkpoint molecule that was overexpressed in several tumor types and that was linked with tumor aggressiveness and poor outcomes when deregulated.

The company said Lu-177-Betabart targeted the four-Ig sub-type of B7-H3, which was the most common sub-type expressed in human tumors.

Radiopharm said that the monoclonal antibody was invented at Houston’s MD Anderson Cancer Center and engineered for shorter blood circulation time and reduced affinity for on-target off-tissue toxicity.

The company said that Radiopharm Ventures was a joint venture between it and MD Anderson Cancer Center.

Radiopharm said it expected phase I/II first-in-human trials of Lu-177-Betabart in multiple tumor types in the US by mid-2025.

The company said that Atomvie’s clinical development expertise, including technology transfer, process and method development, clinical supply and global distribution, provided a “reliable foundation for advancing Lu-177-Betabart from the clinic towards commercialization”, including a new 6,717 square metre facility set to open in early 2025.

Radiopharm chief executive officer Riccardo Canevari said “our collaboration with Atomvie is a significant step forward in our mission to bring innovative radiopharmaceutical therapies to patients”.

Radiopharm fell 0.05 cents or 1.9 percent to 2.6 cents with 5.8 million shares traded.

[OPYL](#)

Opyl says it has a six-month agreement with Commercial Eyes Pty Ltd to provide its Trialkey artificial intelligence-based platform and other services for use in clinical trials. Opyl said it would “receive fees for its services, with payment tied to the commencement of the market analysis work”, but did not disclose the commercial terms of the agreement. Opyl was up 0.1 cents or 5.9 percent to 1.8 cents.

[CLINUVEL PHARMACEUTICALS](#)

Clinuvel says its annual general meeting voted a second strike against its remuneration report, but its spill resolution was defeated by 89.8 percent of the vote.

Last month, Clinuvel said investors would vote on a conditional spill resolution and to increase the aggregate non-executive director remuneration 71.2 percent to \$1,200,000 (BD: Sep 13, 2024).

Today, the company said the remuneration report was defeated by 10,091,433 votes (52.09%) with 9,281,976 votes (47.91%) in favor.

Clinuvel said 2,003,734 votes (10.16%) were in favor of the spill resolution, with 17,715,053 votes (89.84%) against.

The company said the re-election of its four directors were opposed by 4.70 percent to 18.64 percent of the meeting, with the increase in the directors’ fee pool facing 13.63 percent dissent.

According to its most recent notice, Clinuvel had 50,060,680 shares on issue, meaning that the 10,091,433 votes against the remuneration report amounted to about 20.2 percent of the company, sufficient to requisition extraordinary general meetings.

Clinuvel fell 39 cents or 2.7 percent to \$14.11.

[OPTHEA](#)

Opthea says its annual general meeting will vote to issue 13,000,000 options to its chair and non-executive directors.

Opthea said investors would vote to issue chair Dr Jeremy Levin 2,000,000 options, and 2,000,000 options each to non-executive directors Lawrence Gozlan, Dr Susan Orr, Quinton Oswald, Anshul Thakral and Sujal Shah, as well as 1,000,000 options to non-executive director Dr Julia Haller.

The company said the options were subject to “certain vesting conditions and exercise conditions”, would vest in three equal annual tranches, and were exercisable at the closing price on the date of grant, within 10 years.

Opthea said shareholders would vote to re-elect Mr Gozlan and Mr Shah, adopt its remuneration report, approve the issue of shares under its long-term incentive plan, and ratify shares and options.

The meeting will be held online on November 15, 2024 at 9am (AEDT).

Opthea fell one cent or 1.1 percent to 90.5 cents with 1.5 million shares traded.

[NYRADA](#)

Nyrada says it has completed all nine of its pre-clinical studies ahead of its phase I trial of NYR-BI03 for traumatic brain injury and stroke, expected to begin this year.

Nyrada said the pre-clinical studies showed NYR-BI03 was “well tolerated with a favorable safety profile” and it was finalizing its ethics committee regulatory submission.

Nyrada was up 3.6 cents or 36.4 percent to 13.5 cents with 8.5 million shares traded.

PERCHERON THERAPEUTICS

Percheron has requested a trading halt pending an announcement “in relation to a capital raising”.

Trading will resume on October 18, 2024.

Percheron last traded at 13.5 cents.

ANTEOTECH

Anteotech has requested a trading halt pending an announcement “concerning the counterparty [...] for the first commercial order for ultranode battery anode”.

Yesterday, Anteotech said it had received its first commercial order for its Ultranode battery anode technology worth \$40,000 from an unnamed European electric vehicle manufacturer (BD: Oct 15, 2024).

Trading will resume on October 18, 2024 or on an earlier announcement.

Anteotech last traded at 2.6 cents.

ENLITIC

The Sydney-based Pengana Capital Group Ltd says it has become a substantial shareholder in Enlitic with 40,474,040 shares, or 7.66 percent.

Pengana said that on September 2, 2024 it bought 474,040 shares for \$28,505, or six cents a share, and on October 11, 2024 purchased 40,000,000 shares for \$2,000,000, or five cents a share.

Last month, Enlitic said it had “commitments” to raise \$22.5 million at 5.0 cents a share in a placement and share plan for \$1.3 million (BD: Sep 2, 2024).

ARGENT BIOPHARMA (FORMERLY MGC PHARMACEUTICALS)

Argent founder and managing-director Roby Zomer says he has become substantial in the company with 5,292,231 shares, or 9.87 percent.

Mr Zomer said that with HSBC and the Ljubljana, Slovenia-based Chitta Lu Ltd he received 4,000,000 shares for no consideration on October 9 and on October 10, 2024 bought 1,258,500 shares for \$503,400, or 40 cents a share.

Last year, the then MGC shareholders approved the company’s 1,000-to-one consolidation (BD: Oct 26, 2023).

In August, Argent said investors would vote to delist from the ASX, issue 4,000,000 shares to Mr Zomer and 600,000 rights to chair Brett Mitchell (BD: Aug 28, 2024).

Argent was up two cents or 4.9 percent to 43 cents.

NANOSONICS

Nanosonics says directors Dr David Fisher and Geoff Wilson will retire at its annual general meeting on November 12, 2024.

Nanosonics said the search for a suitable replacement director was “well advanced” and it expected to appoint a new director by early 2025.

Nanosonics fell 17 cents or 4.5 percent to \$3.59.

[BIO-MELBOURNE NETWORK](#)

The Bio-Melbourne Network says that it will host a three-part masterclass on essential tools and insights needed to scale ventures sustainably, in November.

The Bio-Melbourne Network said the program, titled 'Vital ventures: Scaling healthtech with sustainable strategies' would be sponsored by the Victoria State Government.

The Network said that the masterclass program was tailored for companies seeking to prepare for key inflexion points in service of being investment-ready, market-ready or exit-ready.

Bio-Melbourne said the forum was a stand-alone event as well as Part A of the masterclass program and would begin at the Science Gallery, Melbourne Theatre, 114 Grattan Street, Carlton on November 26, 2024 from 4pm to 6:30pm (AEDT).

The Network said that Part B would be a workshop at the Monash Conference Centre, Level 7, 30 Collins St, Melbourne on November 27, 2024 from 8:30am to 5pm (AEDT), and Part C would be a series of 30-minute advisory sessions on November 28 and 29, 2024.

For details and registration go to: <https://bit.ly/3BF03wD>.