



# Biotech Daily

Monday June 28, 2021

*Daily news on ASX-listed biotechnology companies*

- \* **ASX FLAT, BIOTECH DOWN: USCOM UP 17%; CYCLOPHARM DOWN 36.5%**
- \* **CYCLOPHARM: FDA LETTER DELAYS TECHNEGAS '9 MONTHS'**
- \* **QBIOTICS RAISES \$35m FOR CANCER, WOUND DRUGS; TOTAL \$85m**
- \* **ATOMO: ACCESS BIO COVID-19 ANTIBODY TEST US EMERGENCY USE**
- \* **WEHI, BOEHRINGER INGELHEIM PARTNER ON CANCER PROTEINS**
- \* **BRANDON \$10m FOR CURRUS CAR-T-CELL SOLID TUMOR DRUGS**
- \* **CARTHERICS LICENCES TOOLGEN CRISPR/CAS9 FOR GENE-EDITING**
- \* **HYDRIX: ANGELMED FDA APPROVAL FOR GUARDIAN BATTERY**
- \* **AMPLIA, GARVAN TRIAL AMP945, GEMCITABINE IN PANCREATIC CANCER**
- \* **NANOSONICS TO LAUNCH AUDITPRO DIGITAL DATA FLOW**
- \* **ANTISENSE, MCRI WORK ON ATL1102 FOR MULTIPLE MUSCLE DISEASES**
- \* **CYNATA APPOINTS DATAPHARM FOR MSC DIABETIC FOOT ULCER TRIAL**
- \* **PHARMAUST: 1 OF 15 DOGS MPL TUMOR REGRESSION; 6 'STABLE'**
- \* **PROBIOTEC COMPLETES \$4m H&H ACQUISITION**
- \* **PAINCHEK RECEIVES \$1.25m FEDERAL MILESTONE**
- \* **ELIXINOL REQUESTS 'PROPOSED ACQUISITION' TRADING HALT**
- \* **VISIONEERING COMPLETES 100-TO-1 CDI CONSOLIDATION**
- \* **PROBIOTEC APPOINTS SIMON GRAY DIRECTOR**
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- \* **ECOFIBRE APPOINTS VANESSA WALLACE DIRECTOR**

## MARKET REPORT

The Australian stock market slipped 0.01 percent on Monday June 28, 2021, with the ASX200 down 0.7 points to 7,307.3 points. Ten of the Biotech Daily Top 40 stocks were up, 23 fell, six traded unchanged and one was untraded. All three Big Caps were up.

Uscom was the best, up 2.5 cents or 17.2 percent to 17 cents, with 706,127 shares traded. Prescient climbed 10.8 percent; Neuren and Patrys were up more than five percent; Opthea and Resonance improved more than three percent; Amplia and Antisense rose more than two percent; CSL was up 1.15 percent; with Clinuvel, Cochlear, Pro Medicus and Resmed up by less than one percent.

Cyclopharm led the falls, down \$1.00 or 36.5 percent to \$1.74, with 945,597 shares traded. Compumedics lost 8.9 percent; Telix fell 7.1 percent; Oncosil was down 5.2 percent; Avita, Dimerix, Mesoblast, Next Science and Optiscan fell four percent or more; Actinogen, Genetic Signatures, Paradigm and Starpharma were down more than three percent; Cynata, Immutep, Nanosonics and Pharmaxis shed more than two percent; LBT, Polynovo and Universal Biosensors were down more than one percent; with Kazia, Medical Developments and Orthocell down by less than one percent.

## CYCLOPHARM

Cyclopharm says that a US Food and Drug Administration complete response letter has delayed approval of Technegas by about nine months.

Cyclopharm said that the FDA was “unable to approve” its new drug application for Technegas in its present form and provided a definitive list of items and recommendations for outstanding elements to be addressed within a 12-month period.

The company said it expected to resolve all elements “with a view to securing approval for commercial sales of Technegas in the US market in 2022”.

Cyclopharm managing-director James McBrayer said that “while the elements in the ... letter are attainable within the required time-frame, we are disappointed with this news of the additional technical information requests”.

Last year, Cyclopharm said its 240-patient, phase III Technegas lung imaging trial was halted after data from 200 patients met the primary efficacy endpoint and in January the Society of Nuclear Medicine and Molecular Imaging called on the FDA to expedite the approval of Technegas (BD: Sep 15, 2020; Jan 22, 2021).

Today, Mr McBrayer said that he had the expected approval timeframe had been extended “by around nine months ...[and] we have complete confidence that we can address these matters and do what is required to expedite this process”.

Cyclopharm said that majority of the technical issues related to better defining and validating the unique characteristics, production and delivery of the Technegas particle, with other issues including specific aspects of crucible manufacturing and dosimetry in adults and children, as well as items identified in the pre-approval inspection in April.

The company said it would continue to service the 60 countries where Technegas had been delivered to more than 4.4 million patients, as well as expand its indications for use beyond pulmonary embolism.

Cyclopharm said it would meet with the FDA in the coming weeks and its guidance on FDA approval had moved from the second half of 2021 to the second half of 2022, which did not “impact the company’s ability to fund the remaining approval process”.

The company said the US was worth about \$US1,801 million a year in revenue.

Cyclopharm fell \$1.00 or 36.5 percent to \$1.74 with 945,597 shares traded.

## QBIOTICS

Brisbane's Qbiotics says it has raised a further \$35 million at 90 cents a share to fund the development of EBC46 for cancer and EBC1013 for wound healing.

In March, Qbiotics said it raised \$50 million from Sydney cornerstone investor TDM Growth Partners at 90 cents a share (BD: Mar 17, 2021)

Today, the company said it placed \$22.55 million to existing sophisticated investors in April and \$12.5 million placement to existing shareholders on June 25, 2021

Qbiotics said the funds would enable human clinical development of the anti-cancer drug candidate tigilanol tiglate, also known as EBC46 and Stelfonta, and wound-healing drug candidate EBC-1013, as well as expand the market for the veterinary use of Stelfonta.

Qbiotics is a public unlisted company.

## ATOMO DIAGNOSTICS

Atomo says the US Food and Drug Administration has granted partner Access Bio emergency use authorization for its rapid antibody test for Covid-19.

Atomo said the Carestart Ez Covid-19 immunoglobulin G (IgG) immunoglobulin M (IgM) rapid antibody test was an immune-chromatographic lateral flow assay intended for the qualitative detection and differentiation of IgM and IgG antibodies to severe acute respiratory syndrome coronavirus-2, the virus that causes Covid-19, in finger prick blood. In 2018, Atomo said it had partnered with Access Bio for HIV tests and last year said it would supply the Seoul, South Korea-based Access Bio two million of its rapid diagnostic tests for Covid-19 antibodies (BD: Jan 24, 2018; Jul 28, 2020)

The company said that the sensitivity for IgG was 97 percent, for IgM 100 percent, with 100 percent specificity for both IgG and IgM "demonstrating excellent performance".

Atomo said the FDA authorization allowed for the point-of-care sales in the US.

Access Bio chief executive officer Young Ho Choi said that as vaccinations accelerated, the demand to check whether or not antibodies were produced was increasing and "our rapid tests will be useful in doctor's offices and clinics in pharmacies".

Atomo was up 5.5 cents or 40.7 percent to 19 cents with 29.8 million shares traded.

## THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says it will work with Germany's Boehringer Ingelheim on cancer drugs using "targeted protein degradation".

WEHI said the collaboration brought the two organizations' expertise in the biology and therapeutic targeting of "inhibitor of apoptosis proteins", protein degradation and drug discovery to target cancer-causing proteins.

The Institute said that inhibitor of apoptosis proteins (IAPs) could target disease-causing proteins for destruction.

WEHI said targeted protein degradation used existing protein recycling machinery within the cell to destroy a disease-causing protein of interest, as compared to traditional drug discovery using small molecule inhibitors to bind to proteins and block their action.

The Institute's Prof John Silke said Boehringer Ingelheim had "extensive experience in drug discovery and development, making it the perfect partner ... [and] together, we can apply this innovative IAP-based approach to a number of 'undruggable' disease targets that have proven intractable to more traditional drug discovery approaches".

The Institute said that after the collaboration Boehringer Ingelheim would be responsible for clinical development, regulatory approvals, and commercial activities, with WEHI to receive milestone payments and royalties on sales, with the terms undisclosed.

## BRANDON CAPITAL, CURRUS BIOLOGICS

Brandon Capital says it has invested \$10 million in Currus Biologics to develop chimeric antigen receptor (CAR) T-cell therapies for solid tumors.

Brandon said the funding was through its Medical Research Commercialisation Fund and Uniseed, the Beat technology was based on research from Melbourne's Peter MacCallum Cancer Centre and Currus was "the first investor-led spinout" from the Centre's research. The company said that Currus had developed "bispecific engagers of antigen-presenting cells and T-cells" (Beat) technology as a combination therapy with CAR-T cells targeting the treatment of solid tumors, such as breast, ovarian and pancreatic cancers.

Brandon said that CAR-T therapies were "revolutionary" for severe, advanced blood-borne cancers, such as leukaemia and lymphoma, with remission rates of up to 94 percent, but were less useful at treating solid tumors, which made up 90 percent of all cancers.

The company said that CAR-T cell therapy worked by extracting a patient's T-cells and genetically engineering them to produce chimeric antigen receptors (CARs) that could be used to specifically seek out and destroy cancer cells after infusion back into the patient.

Peter MacCallum head of the immune innovation Prof Michael Kershaw said that Beat recognized and simultaneously bound to the CAR-T-cells, as well as "professional antigen presenting cells", enabling their direct interaction, in turn activating T-cells, enabling them to then seek out and destroy solid tumor cells.

"Our research findings in animal models indicate that one infusion of the treatment is expected to be effective in the treatment of solid tumors," Prof Kershaw said.

Currus chief executive officer Sam Cobb said that there was "significant global interest in how CAR-T therapies can be used to target the full spectrum of cancers".

"Using CAR-T therapies to treat solid tumors with the Beat technology could have similar impacts in this field, as we have seen for patients with liquid tumors," Ms Cobb said.

Currus is a private company.

## CARTHERICS PTY LTD

Cartherics says it has licenced the world-wide rights to Toolgen Inc's patents relating to the use of CRISPR/Cas9 for genome editing.

In 2019, the privately-owned, Melbourne-based Vivazome said it had a collaboration with the Seoul, South Korea-based Toolgen to explore gene-editing of cells for enhanced exosome production using CRISPR-Cas9, or clusters of regularly interspaced short palindromic repeats (CRISPR)-associated protein 9 to introduce gene edits into selected cell types (BD: Aug 27, 2019).

Today, Cartherics said it had world-wide rights to Toolgen's intellectual property relating to the use of CRISPR/Cas9 for genome editing involving the insertion of chimeric antigen receptor (CAR) genes and deletion of specific genes that code for proteins that inhibit immune cell function.

The company said it intended to apply the technology to the development of autologous gene-edited CAR-T-cells and allogeneic gene-edited CAR-NK (natural killer) cells derived from induced pluripotent stem cells targeting the TAG-72 tumor associated antigen.

Cartherics chief executive officer Prof Alan Trounson said Toolgen was "one of the pioneering companies in the gene-editing space".

The company said the terms of the licence were confidential but it would pay Toolgen up-front fees, milestones and royalties on sales, as well as provide equity in the company.

Cartherics is a private company.

## [HYDRIX](#)

Hydrix says the US Food and Drug Administration has approved an upgraded battery for the Angel Medical Systems Guardian cardiac monitor.

Hydrix said the Eatontown, New Jersey-based Angel Medicals Guardian was the “world’s only FDA-approved implantable cardiac monitoring device that alerted patients of an impending acute coronary syndrome event”.

Hydrix was up 5.5 cents or 35.5 percent to 21 cents with 58.6 million shares traded.

## [AMPLIA THERAPEUTICS](#)

Amplia says that with Sydney’s Garvan Institute of Medical Research it will fund a phase II trial of its AMP945 with gemcitabine for pancreatic cancer.

In March, Amplia said it will collaborate with the Garvan to develop its focal adhesion kinase (FAK) inhibitor AMP945 for pancreatic cancer (BD: Mar 18, 2021).

Today, the company said that using Garvan’s clinical research network, it would design and plan the phase II pancreatic cancer trial, which was expected to begin “later this year”. Amplia said under the two-year collaboration agreement it would receive initial rights to participate in FAK inhibitor-related research projects in combination with other therapeutic products for the treatment of cancer.

Amplia was up half a cent or 2.2 percent to 23 cents.

## [NANOSONICS](#)

Nanosonics says it will launch its Auditpro infection prevention digital platform at the Association for Professionals in Infection Control on June 28, 2021.

Nanosonics said Auditpro would improve and standardize infection control compliance for different medical instruments to support management of healthcare-acquired infection risks and support patient care.

Nanosonics chief operating officer Michael Kavanagh said that Auditpro was “one of the new products previously foreshadowed and represents the first product to be brought to market from our compliance and traceability [research and development] program”.

Mr Kavanagh said Auditpro was “comprised of a mobile scanning device coupled with a subscription to a browser-based application for users” and delivered “real time access” to compliance and traceability data for customers and was a new revenue stream.

“The first application focuses on ultrasound procedures, with the new handheld device designed to be coupled with every ultrasound console at point of care,” Mr Kavanagh said.

Nanosonics has commercialized its Trophon EPR ultrasound probe cleaning system.

Nanosonics fell 13 cents or 2.2 percent to \$5.84 with one million shares traded.

## [ANTISENSE THERAPEUTICS](#)

Antisense says it has a collaboration with the Murdoch Children’s Research Institute to explore the use of its ATL1102 in multiple muscle diseases.

Antisense said the Melbourne-based Murdoch Children’s Research Institute’s scientific researchers, Dr Peter Houweling and Prof Shireen Lamande would investigate the potential of ATL1102 to treat immune-mediated inflammatory muscle damage.

Antisense was up half a cent or 2.6 percent to 19.5 cents with 1.4 million shares traded.

## CYNATA THERAPEUTICS

Cynata says it has appointed Datapharm Australia as the contract research organization for a trial of Cymerus mesenchymal stem cells for diabetic foot ulcers.

Earlier this month, Cynata said it would use the Adelaide-based Tekcyte's wound dressing for a diabetic foot ulcer trial and had an option to buy the technology (BD: Jun 3, 2021).

Today, the company said it had made "substantial progress" on the trial design and endpoint selection and the appointment of Sydney's Datapharm was "an important milestone toward commencing the trial".

Cynata said Datapharm would support the conduct and management of the trial but the value of the contract was "not considered material from a quantitative perspective".

The company said the regulatory, ethics clearance processes and completion of trial start-up activities were currently underway and patient enrolment was expected to begin by the end of the year.

Cynata fell 1.5 cents or 2.9 percent to 50.5 cents.

## PHARMAUST

Pharmaust claims its 15-dog monepantel cancer trial achieved the two interim endpoints of objective tumor regression and increased progression-free survival.

Pharmaust said the one of the dogs had tumor regression with some tumors resolving completely and six of the first 15 pet dogs showed objective stable disease or better during the 28-day trial period which was "a compelling outcome".

The company said that previously published mean and median times for untreated dogs showed that eight of the 15 dogs would have been put down by day-30 due to the "aggressively progressive disease and poor quality of life".

Pharmaust said that three dogs were withdrawn from the trial, two with advanced and extensively disseminated disease, and one with advanced and less extensively disseminated disease, with 12 completing the 28-day trial.

The company said that from available reports, six dogs continued with monepantel alone or in combination with prednisolone.

Pharmaust chief scientific officer Dr Richard Mollard said that "in addition to the standard measurements of target superficial lymph nodes that are characteristic of many such trials, we incorporated comprehensive thoracic x-ray and abdominal ultrasound analyses into the trial design".

"This means that designation of stable disease in this trial really means comprehensive stable disease, not superficially stable disease as per many other trials where progression might be hidden somewhere else in the body," Dr Mollard said.

Pharmaust was up 0.3 cents or 3.4 percent to 9.2 cents with 1.6 million shares traded.

## PROBIOTEC

Probiotec says it has acquired the assets and business of Sydney-based H&H Packaging for total cash proceeds of up to \$4 million.

Probiotec said the acquisition would add plastic moulding capabilities, deliver new customers to the company which include the capability to service industrial, chemical and agricultural markets and widening its overall reach.

The company said H&H was expected to generate revenue of about \$6 million and earnings before interest, taxes, depreciation, and amortization of about \$1 million for the 12 months to June 30, 2021.

Probiotec was up 12 cents or 5.7 percent to \$2.24.

### [PAINCHEK](#)

Painchek says it will receive a \$1.25 million milestone payment from the Federal Government's Department of Health for its pain assessment technology in aged care. Earlier this month, Painchek said signing 49,000 beds in April and May had taken the total using its pain test to 127,000 beds, or 60 percent of the Australian residential aged care market (BD: Jun 3, 2021).

Today the company said the 127,000 beds included 82,982 dementia-specific beds funded by the Federal Government that were projected to be a \$1.25 million "milestone payment" expected by June 2021 and recognized as government funded revenue in the 12 months to June 30, 2021.

Painchek said it expected to generate \$5.5 million as its annual recurring revenue after the Government funded 12-month period.

Painchek was up 0.1 cents or 1.7 percent to 6.1 cents with 4.1 million shares traded.

### [ELIXINOL WELLNESS \(FORMERLY ELIXINOL GLOBAL\)](#)

Elixinol has requested a trading halt pending an announcement "regarding the proposed acquisition of Cannacare Health GmbH".

Trading will resume on June 30, 2021 or on an earlier announcement.

Elixinol last traded at 13 cents.

### [VISIONEERING TECHNOLOGIES](#)

Visioneering says it has completed a 100-to-one consolidation reducing the Chess depositary interests (CDIs) on issue from 2,264,679,811 CDIs to 22,647,141 CDIs.

Visioneering was unchanged at \$1.10.

### [PROBIOTEC](#)

Probiotec says it has appointed Simon Gray as an independent, non-executive director, effective from July 1, 2021.

Probiotec said Mr Gray had a "strong background in law, financial services and markets, risk and strategy".

The company said Mr Gray was previously a director at Morgans Financial and an executive and Partners.

Probiotec said Mr Gary was currently the chair of the Australian Securities and Investments Commission's markets disciplinary panel.

### [RESONANCE HEALTH](#)

Resonance says executive director Mitchell Wells has been appointed managing-director, effective from July 2, 2021.

Earlier this month chief executive officer Alison Laws resigned "due to unplanned personal family obligations" (BD: Jun 4, 2021)

Resonance said Mr Wells has been with the company since April 2017 initially providing strategy, contract, and corporate advisory services, and in 2018 was appointed a director.

The company said Mr Wells previously worked for Amadeus Energy as chief operating officer and later chief executive officer, and according to his LinkedIn page, Mr Wells holds a Bachelor of Commerce and Bachelor of Laws from Perth's Murdoch University.

Resonance was up half a cent or 3.2 percent to 16 cents.

## ECOFIBRE

Ecofibre says it has appointed Vanessa Wallace as a director and deputy chair, effective from July 1, 2021.

Ecofibre said Ms Wallace had about 30 years of experience as a strategy management consultant with a focus on financial services, health and consumer product industries.

The company said Ms Wallace previously co-led Booz & Co in Japan, was an early-stage investor in the health sector and was the founding chair of Drop Bio.

According to her LinkedIn page, Ms Wallace holds a Bachelor of Commerce from Sydney's University of New South Wales and Master of Business Administration from Lausanne, Switzerland-based Institute for Management Development Business School.

Ecofibre fell 1.5 cents or 1.9 percent to 76.5 cents.