Biotech Daily

Wednesday April 9, 2025

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: CYNATA UP 6%; ACTINOGEN DOWN 10%**

*** HEADSAFE FDA NUROCHEK CONCUSSION TEST CLEARANCE**

*** POLYNOVO RECORD $12m MONTHLY REVENUE; 'NO TARIFF IMPACT'**

*** RESPIRI 'RECENT US DEVELOPMENTS REINFORCE STRATEGY'**

*** IMPEDIMED EXPECTS 'NO MATERIAL IMPACT FROM US TARIFFS'**

*** AUSTCO $7m FOR DISTRIBUTOR GUILD & SPENCE**

*** IDT $3.2m NACUITY NPI-001 DEAL RESTARTS SMALL MOLECULE PLANT**

*** ORTHOCELL BRAZIL STRIATE+ APPROVAL**

*** NYRADA OKAY TO DOSE 2nd PHASE I NYR-BI03 COHORT**

*** AMPLIA STARTS US NARMAFOTINIB, FOLFIRINOX PANCREATIC CANCER TRIAL**

*** OSTEOPORE EU ORTHOPAEDIC, CRANIAL IMPLANT APPROVAL**

*** WEHI: 'DRUG PREVENTS LONG COVID-19 SYMPTOMS, IN MICE'**

*** PYC $13m UNDERWRITER 'LIQUIDITY ISSUE EXTENSION'**

*** ARGENT: DAVID TRADING TO OPERATE MALTA FACTORY**

*** PINNACLE REDUCES TO 5.1% OF FISHER & PAYKEL**

*** REGAL FUNDS TAKES 13.8% OF ALTERITY**

MARKET REPORT

The Australian stock market lost 1.80 percent on Wednesday April 9, 2025, with the ASX200 down 135.0 points to 7,375.0 points. Just three of the Biotech Daily Top 40 companies were up, 31 fell, four traded unchanged and two were untraded.

Cynata was the best of the three, up one cent or 5.6 percent to 19 cents, with 219,221 shares traded. Starpharma climbed 5.5 percent; Curvebeam rose 4.4 percent; with Pro Medicus up by 0.1 percent.

Actinogen led the falls, down 0.3 cents or 10 percent to 2.7 cents, with 20.5 million shares traded. Mesoblast and Polynovo lost more than eight percent; EBR, Resonance and Syntara were down more than seven percent; Immutep, Medical Developments and Neuren shed six percent or more; Clarity, Clinuvel, CSL and Emvision were down five percent or more; Cyclopharm, Dimerix, Genetic Signatures, Imugene, Medadvisor and Universal Biosensors fell four percent or more; 4D, Compumedics, Nova Eye and Paradigm were down more than three percent; Avita, Cochlear, Impedimed, Orthocell and Prescient shed more than two percent; with Aroa, Nanosonics, Proteomics, Resmed, SDI and Telix down by more than one percent.

HEADSAFE MFG PTY LTD

Headsafe says it has US Food and Drug Administration clearance for its Nurochek-Pro portable, wearable concussion diagnostic headset.
Last year, the Sydney-based Headsafe said it hoped to raise $5 million for its Nurochek, two-minute, wearable, concussion test (BD: May 8, 2024).
At that time, the company said the headset cost $4,500 with a fee of $45 per test.
Today, Headsafe chief executive officer Dr Adrian Cohen told Biotech Daily that the Nurochek-Pro approval was “the third FDA clearance for the product family”.
“The business model involves test fees, so it is like software as a service,” Dr Cohen said.
Headsafe said Nurochek-Pro had a front visor that stimulated the retina using light and a rear section measuring the electrical response of the brain using electrodes, with artificial intelligence (A.I.) software that classified and securely stored readings.
The company said Nurochek-Pro was “intended for prescription use in healthcare facilities for subjects aged between 12 and 44 years old for the aid in diagnosis of mild traumatic brain injury in conjunction with a standard neurological assessment”.
Headsafe said the device would be eligible for reimbursement under a number of existing US insurance treatment codes.
The company said it planned to begin distributing Nurochek-Pro in the US “later this year through established industry sales and distribution networks for medical devices”.
Dr Cohen said that current concussions assessment methods could “be expensive, time consuming, cumbersome and highly subjective and we believe Nurochek’s ability to deliver objective results in just two minutes is a game changer”.
“Apart from being easy to use, Nurochek does not require a baseline, or previous reading, making it ideal for healthcare environments,” Dr Cohen said.
Headsafe is a private company.

POLYNOVO

Polynovo says it has “record monthly sales” to March 31, 2025 of $11.9 million, with $12.4 million in revenue and does not expect a material impact from the US tariffs.
In February, Polynovo said it had record revenue for the six months to December 31, 2024 from sales of its Novosorb bio-resorbable dermal scaffold for burn wound repair, up 24.7 percent to $59,867,000, with record profit of $3,338,000 (BD: Feb 24, 2025).
Today, the company said record US monthly sales were up 92.6 percent on the prior corresponding period to $9.3 million, with $900,000 in monthly sales from the UK, $133,000 in India and $2.6 million from other territories.
Polynovo said total monthly revenue was up 48.5 percent on the previous corresponding period to $12.4 million and that it was “profitable, with results in-line with internal plans”.
The company said it continued to invest in expanding Novosorb use to indications including burn, plastics and reconstruction, limb salvage, orthopaedic and general surgery.
Last week, the US White House said President Donald Trump used emergency powers to “impose a 10 percent tariff on all countries”, with some goods including pharmaceuticals not subject to the reciprocal tariff (BD: Apr 3, 2025).
Today, Polynovo said that medical devices were not exempt from the tariffs.
The company said it had about 10 months of inventory in the US and “does not expect a material impact on the business as a result of these tariffs”.
Polynovo chair David Williams said the company had “an enviable array of ways to expand indications in existing markets, expand our international footprint, and introduce new products to drive revenue growth”.
Polynovo fell nine cents or 8.5 percent to 96.5 cents with 9.1 million shares traded.

RESPIRI

Respiri says “recent developments in US health policy and international trade reinforce the company’s commercial strategy and operational robustness” (see above).
Respiri said that US Secretary of Health and Human Services Robert F Kennedy Junior “spotlighted the transformative potential of artificial intelligence (A.I.), telehealth and virtual care platforms in providing efficient and effective patient services, particularly in rural and underserved communities”, and Mr Kennedy “advocated strongly for scaling these technologies through the healthcare system”.
The company said Mr Kennedy’s policy direction “directly supports [our] connected care business model and the adoption of its [remote patient monitoring]-enabled platforms”.
Respiri said that the US tariffs on Chinese-manufactured medical devices would “have no material impact on business operations” and that it had more than two years’ worth of inventory of its Wheezo remote patient monitoring device in the US.
The company said that “although the tariff may increase supply costs by about $US30 ($A50) per other medical devices, the company will absorb the increase internally”.
Respiri said the costs were “less than half a month’s worth of … reimbursement revenue per patient” and absorbing the costs ensured no change to client pricing or margin.
Respiri managing-director Marjan Mikel said “comments from Mr Kennedy highlight a sea change in US healthcare, one where virtual care is no longer a ‘nice-to-have’, but a national priority”.
“Respiri is at the forefront of this shift, delivering scalable, clinically integrated [remote patient monitoring] solutions that improve outcomes and reduce cost,” Mr Mikel said.
“Meanwhile, our prudent inventory management ensures we remain relatively immune to supply-side disruption from recent US tariff change,” Mr Mikel said.
Respiri was up 0.3 cents or 10.3 percent to 3.2 cents with one million shares traded.

IMPEDIMED

Impedimed says it “does not anticipate any material impact on its business or supply chain arising from … [the US tariff] changes in the short to medium term”.
Impedimed said its Sozo device and a “substantial number of components” used in the device were manufactured in the US, and it was “holding sufficient inventory of finished goods and components to shield its supply chain from near term external shocks”.
Impedimed said that due to “the uncertain and evolving impact of the US tariff policies … the company will continue to monitor these events”.
Impedimed fell 0.1 cents or 2.8 percent to 3.5 cents with 2.7 million shares traded.

AUSTCO HEALTHCARE

Austco says it will pay $NZ7,966,035 ($A7,375,000) in cash to acquire its nurse call products distributor Guild & Spence Technologies, as well as an earn-out payment.
Austco said it would pay Auckland’s Guild & Spence an earn-out based on performance between completion of the deal, expected about June 1, 2025, until December 31, 2026.
The company said 75 percent of the earn-out would be paid in scrip and would be calculated as 3.5 times Guild & Spence’s earnings before interest, taxes, depreciation and amortization (Ebitda) minus the up-front cash payment.
Austco said Guild & Spence specialized “in the installation, service and maintenance” of its Nurse Call technology as well as custom workflow, real-time locating security, closed-circuit television (CCTV) and access control systems for healthcare.
Austco fell one cent or 3.9 percent to 24.5 cents.

IDT AUSTRALIA

IDT says a $3.2 million contract to manufacture Nacuity Pharmaceuticals' NPI-001 tablets for retinitis pigmentosa allows it to recommission its small molecule plant.

IDT said the Dallas, Texas-based Nacuity had US Food and Drug Administration fast track designation for NPI-001, or N-acetyl-cysteine amide, to treat retinitis pigmentosa and would pay an initial $3.2 million for the contract, which was expected to conclude by 2027 and allowed for annual extensions.

The company said the deal aimed to scale-up the production of the active ingredient of NPI-001 10-fold to 200kg and production of the finished drug of 1,000,000 tablets.

IDT said that the small molecule active pharmaceutical ingredient factory was the largest of its type in Australia.

The company said that NPI-001 manufacturing activities were underway and scheduled for completion this year.

IDT said the contract was "a significant milestone in IDT's strategy to expand its pharmaceutical manufacturing capabilities and leverage its expertise in the production of ground-breaking therapies".

IDT chief executive officer Paul McDonald said the company was "excited to partner with Nacuity on the manufacture of this promising therapy for patients with [retinitis pigmentosa], especially when there is no standard treatment for the disease".

"Our ability to support innovative clients from clinical trials to commercialization is one reason why we have such a high rate of return work," Mr McDonald said.

IDT was up 1.5 cents or 16.7 percent to 10.5 cents.

ORTHOCELL

Orthocell says the Brazilian Health Regulatory Agency has approved its Striate+ dental guided bone and tissue regeneration device.

Last month, Orthocell said Striate+ was approved for use in the US, Australia, New Zealand, Europe, the UK, Canada and Singapore, and that it had its first sale in the Germany, Austria and Switzerland region (BD: Mar 26, 2025).

Today, the company said that commercial sales of Striate+ were expected to begin in Brazil by 2026.

Orthocell managing-director Paul Anderson said the company was "delighted to receive regulatory approval for Striate+ in Brazil".

"This approval provides additional validation of Orthocell's high-quality products, manufacturing processes and quality systems," Mr Anderson said. "Moreover, it enhances our ability to drive revenue growth as our distribution partner expands into global markets."

"Importantly, we remain well capitalized to roll out our expansion plans for our collagen regenerative membranes Striate+ and Remplir in eight jurisdictions throughout the world," Mr Anderson said.

Orthocell fell 3.5 cents or 2.7 percent to $1.255 with 1.8 million shares traded.

NYRADA

Nyrada says the safety review committee found no issues in the first dosed cohort of its phase I trial of NYR-BI03 and that it would proceed to dosing the second cohort.

In February, the company said the dose-escalating trial would include five cohorts of eight participants, each receiving intra-venous doses over three hours of either NYR-BI03 or placebo, with six active and two placebo participants per cohort (BD: Feb 7, 2025).

Nyrada was up half a cent or five percent to 10.5 cents.

AMPLIA THERAPEUTICS

Amplia says it has begun “trial initiation activities” for an about 60-patient, US phase Ib/IIa trial of narmafotinib (AMP945) with Folfirinox chemotherapy for pancreatic cancer.
Last year, Amplia said that the US Food and Drug Administration approved its investigational new drug application for its separate 50-patient, ‘Accent’, phase IIa trial of narmafotinib focal adhesion kinase inhibitor with gemcitabine and Abraxane for pancreatic cancer (BD: Jan 21, 2024).
Last month, the company said the FDA had agreed that proposed changes to the ‘Accent’ trial appeared “reasonable”; and later, said interim data from the trial showed 13 patients had more than 30 percent tumor size reduction (BD: Mar 3, Mar 27, 2025).
Today, Amplia said that it would open the separate trial in the US under its investigational new drug application to study narmafotinib with Folfirinox (5-fluorouracil, leucovorin, irinotecan and oxaliplatin) in patients with pancreatic cancer.
The company said part A of the trial would dose patients with a range of narmafotinib doses taken once daily with Folfirinox administered every 14 days to study safety, tolerability and pharmaco-kinetics.
Amplia said part A of the trial would be followed by part B, which would administer patients with two doses of the combination found in part A to be the optimal dose.
Amplia managing-director Dr Chris Burns told Biotech Daily part A of the trial would enrol about 20 patients, with about 40 patients expected in part B.
The company said that it had an agreement with a “large multinational contract research organization” to co-ordinate US trial activities and manufacture capsules for the trial, including selecting sites at US hospitals.
Amplia said it would include up-to seven Australian trial sites to “ensure timely recruitment for the trial”.
Dr Burns said the company was “extremely excited to have signed up a world-class [contract research organization] to co-ordinate running this trial and to have started engaging with trial sites”.
“This represents an important next step in the development of narmafotinib by exploring the potential of the drug in combination with another widely used pancreatic cancer treatment,” Dr Burns said.
Amplia was unchanged at 5.3 cents.

OSTEOPORE

Osteopore says the European Union Medical Device Regulation has approved its customized orthopaedic and cranial implants.
In 2023, Osteopore said it had European Union Medical Device Regulation approval for its Osteomesh, Osteoplug and Osteoplug-C products (BD: Apr 27, 2023).
Today, the company said the additional approval allowed it to offer “high-value, custom implants to Europe, in addition to off-the-shelf implants”.
Osteopore said Singapore’s Zimmer Biomet Holdings Inc would distribute the customized implants in Europe (BD: Jul 16, 2024).
Osteopore chief executive officer Dr Yujing Lim said European approval was “in step with our strategy to improve access to our high-value solutions”.
“Our custom orthopaedic implants have already demonstrated transformational effects on patients in earlier publications,” Dr Lim said.
Osteopore was up 1.5 cents or 93.75 percent to 3.1 cents with 85.0 million shares traded.

THE WALTER & ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says an anti-viral drug compound targeting the PLpro protein can treat acute Covid-19 and prevent long Covid-19 symptoms, in mice.

WEHI said a study of its anti-viral compound targeting the protein PLpro, or nidoviral papain-like protease, showed the drug protected mice from long-term brain and lung dysfunction, key symptoms of long Covid-19.

The Institute said the study found that the compound could "treat Covid-19 with better efficacy than Paxlovid, the leading Covid-19 treatment", which was currently only recommended for people considered at risk of severe disease.

The Institute said long Covid-19, or post-acute sequelae of Covid-19 was a "chronic condition characterized by symptoms that last for weeks or months after contracting Covid-19" and that symptoms included breathing difficulties, brain fog and chronic fatigue.

WEHI said that "despite millions of people worldwide reporting these symptoms, the cause of long Covid-19 remains largely unknown and there is no approved treatment for the disease".

The Institute said its researchers would continue to work with the Centre for Drug Candidate Optimization and the Monash Institute of Pharmaceutical Sciences to evaluate the bio-pharmaceutical properties of the anti-viral compound.

The study, titled 'A novel PLpro inhibitor improves outcomes in a pre-clinical model of long COVID' was published in the journal Nature Communications, with the full article available at: https://www.nature.com/articles/s41467-025-57905-4.

WEHI laboratory head Dr Marcel Doerflinger said "with five percent of people who contract Covid-19 going on to develop long Covid-19, the disease has morphed into a silent pandemic where millions are battling symptoms with more questions than answers".

Study co-author Dr Shane Devine said the research provided "the first evidence to prove PLpro is a powerful new drug target for Covid-19 treatments, while also showing its potential ability to treat the virus with unprecedented efficacy".

"The Sars-Cov-2 virus also continues to mutate, meaning it's only a matter of time until Paxlovid will no longer work," Dr Devine said.

WEHI said a Paxlovid limitation was that it required two compounds to interact with each other to be effective, meaning it could interfere with other medications.

"Paxlovid and other anti-virals in the market target Mpro and have these same issues, highlighting the urgent need for more research to enhance Covid-19 treatments that can provide greater access to more patients," Dr Devine said.

PYC THERAPEUTICS

PYC says the underwriter of $13 million from its $146 million rights offer has advised it of a "liquidity issue", with the payment expected to be received by April 30, 2025.

Last month, PYC said it had raised $91 million at $1.25 a share in the institutional component of its up-to $146 million, one-for-four, entitlement offer, with a $55 million retail offer underwritten by existing shareholders to follow (BD: Feb 19, 2025).

Last month, the company said that its retail rights offer raised $9.3 million, taking the total to $100.3 million with a $46 million underwritten shortfall (BD: Mar 18, 2025).

Today, the company said it had received about $133 million and was seeking "payment guarantees and a bond to offset against any potential failure to complete by the underwriter".

PYC said it had "reserved its rights under the underwriting agreement with respect to the outstanding liability and will consider the underwriter's request in due course".

PYC fell six cents or 5.7 percent to 99.5 cents.

ARGENT BIOPHARMA (FORMERLY MGC PHARMACEUTICALS)

Argent says it has an exclusive, 49-year deal for David Trading Ltd to operate its Malta factory and continue production of its Cimetra for neurological and immune disorders.
In 2018, the-then MGC said it raised $5,000,000 in a placement at seven cents a share to fund the marijuana production and cultivation facility in Malta (BD: Apr 11, 2018).
In 2021, the company said it completed construction and the implementation phase of its Cimetra production factory in Malta, following a EUR3.1 million (then about $A4.8 million) cash grant from Malta Enterprise to fund the majority of the costs of construction and equipment (BD: Nov 3, 2021).
Last month, Argent said it would move manufacturing of its marijuana Cannepil and Cognicann to the North Macedonia-based ECC Pharm (BD: Mar 5, 2025).
Later, the company said SK-Pharma chief executive officer Dr Shlomo Sadoun would "facilitate a commercial transaction" of its Malta factory for a minimum $US1 million ($A1.7 million) (BD: Mar 12, 2025).
Today, Argent said the deal included an option for the London-based medical marijuana producer David Trading to acquire the facility for $US500,000 ($A834,195) and a $US1 million ($A1.7 million) share swap with Argent.
The company said David Trading would assume "full responsibility and financial liability for the operation of the facility, including managerial decisions, maintenance, staffing, insurance, and permit renewals, while also taking on all debts and liabilities incurred from the signing date forward".
Argent said David Trading would continue to produce Cimetra for the company at a 25 percent increased cost, and introduce "additional products from its portfolio to the facility's production line upon receiving necessary regulatory approvals, aiming to transform the facility into a profitable asset".
The company said that the proposed disposal of the Malta facility would "not have a material impact on its consolidated total assets, total equity interests, revenue, or earnings before interest, tax, depreciation, and amortization".
Argent was up half a cent or 2.8 percent to a post-1000-to-one consolidation 18.5 cents.

FISHER & PAYKEL HEALTHCARE

Pinnacle Investment Management Group says it has reduced its shareholding in Fisher & Paykel from 36,059,206 shares (6.1954%) to 30,222,955 shares (5.1562%).
The Brisbane-based Pinnacle said it bought and sold shares between October 13, 2023 and April 4, 2025, with the single largest sale 1,545,649 shares on February 27, 2025 for $53,083,723, or $34.34 a share.
Fisher & Paykel fell 44 cents or 1.4 percent to $30.59 with 416,408 shares traded.

ALTERITY THERAPEUTICS

The Sydney-based Regal Funds Managements Pty Ltd says it has become a substantial shareholder in Alterity with 1,255,948,179 shares, or 13.76 percent.
Regal Funds said that between February 17 and April 4, 2025 it bought a total 1,262,748,179 shares for $13,870,300, or 1.1 cents a share.
Alterity was unchanged at 0.7 cents with 37.8 million shares traded.