# Biotech Daily

Monday December 9, 2024

*Daily news on ASX-listed biotechnology companies*

*** ASX FLAT, BIOTECH DOWN: IMPEDIMED, PRESCIENT UP 7%;**
**- PARADIGM DOWN 8%**

*** GHANA APPROVES MDGH MOXIDECTIN FOR RIVER BLINDNESS**

*** S&P PROMOTES CLARITY, ECHO IQ**

*** PARADIGM RAISES $16m; 'PHASE III TRIAL ENOUGH FOR TGA APPROVAL'**

*** NYRADA PLAN RAISES $85k OF HOPED-FOR $1m; TOTAL $4.2m**

*** INDONESIA OKAYS RECCE PHASE III R327 DIABETIC FOOT INFECTION TRIAL**

*** BTC $3.6m PA FOR CORCYM AUSTRALIA, NZ HEART VALVE BUSINESS**

*** CAMBIUM FDA ELATE OCULAR FAST TRACK STATUS**

*** FIVEPHUSION LICENCES WOLLONGONG UNI DRUG DELIVERY SYSTEM**

*** ECHO IQ CPT CODE REIMBURSES ECHOSOLV UP-TO $235**

*** CYCLOPHARM: 'TECHNEGAS GOOD FOR PLANNING LUNG TRANSPLANTS'**

*** ACTINOGEN TREATS 1st US PHASE IIb/III ALZHEIMER'S PATIENT**

*** BLINKLAB TO RELEASE 4.15m ASX ESCROW SHARES**

## MARKET REPORT

The Australian stock market edged up 0.02 percent on Monday December 9, 2024, with the ASX200 up 2.1 points to 8,423.0 points. Thirteen of the Biotech Daily Top 40 stocks were up, 17 fell, nine traded unchanged and one was untraded. All four Big Caps rose.

Impedimed was the best, up 0.4 cents or 7.4 percent to 5.8 cents, with five million shares traded, followed by Prescient up 7.3 percent to 4.4 cents, with 367,642 shares traded. Avita rose seven percent; EBR climbed 6.6 percent; Starpharma was up 4.55 percent; Cyclopharm was up 3.7 percent; Clarity and Resmed rose more than two percent; Alcidion, Dimerix, Immutep and Medical Developments were up more than one percent; with Cochlear, CSL, Nanosonics, Polynovo and Pro Medicus up by less than one percent.

Paradigm led the falls (see below), down 4.5 cents or 7.8 percent to 53.5 cents, with 7.4 million shares traded. Cynata, Syntara and Universal Biosensors fell more than four percent; Micro-X lost 3.2 percent; Clinuvel and Opthea shed more than two percent; 4D Medical, Amplia, Percheron and Prescient were down one percent or more; with Aroa, Emvision, Mesoblast, Neuren, Orthocell and Telix down by less than one percent.

## MEDICINES DEVELOPMENT FOR GLOBAL HEALTH

Medicines Development for Global Health says it has Ghana Food and Drugs Authority approval for its moxidectin 2mg oral tablet for river blindness.

The Melbourne-based not-for-profit Medicines Development for Global Health (MDGH) said Ghana was the "first river blindness-endemic country to approve moxidectin".

In 2018, the company said it had US Food and Drug Administration approval for oral moxidectin 8mg for river blindness or onchocerciasis in patients aged 12 years and older (BD: Jun 14, 2018).

In 2019, MDGH said the Copenhagen-based Novo Nordisk bought its priority review voucher, but did not disclose the price (BD: Aug 13, 2019).

MDGH media spokesman Dr George Rugarabamu told Biotech Daily that the Ghana approval was for adults and children over the age of four years.

Dr Rugarabamu said that moxidectin came in a 2mg tablet and people aged eight years and over would be given four of the 2mg tablets, with younger children given two tablets.

The company said river blindness was caused by the parasitic worm, Onchocerca volvulus and was spread through the worm's larvae, microfilariae, which caused severe itching, skin changes and could lead to visual impairment, including permanent blindness.

MDGH said the World Health Organization and endemic countries currently targeted the elimination of parasite transmission through mass administration of ivermectin.

The company said moxidectin reduced "skin microfilariae levels more profoundly and for longer than ivermectin" was expected to accelerate elimination of parasite transmission.

MDGH said it would provide moxidectin at cost-plus pricing, without profit, to low-and-middle income countries.

The company said that more than 200 million people were at risk of river blindness infection in 29 African countries.

MDGH said it would conduct a community treatment program in the Twifo Atti-Morkwa district, 150km west of the Ghanan capital Accra, in January 2025; with the district identified by the Ghana Health Service a priority for moxidectin after higher-than-expected disease prevalence was found following multiple rounds of ivermectin administration.

The company said the approval was "an important step forward in efforts towards elimination goals".

MDGH said the development and delivery of moxidectin was supported by the UNICEF (United Nations Children's Fund), UNDP (United Nations Development Programme), the World Bank and the World Health Organization Special Programme for Research and Training in Tropical Disease.

MDGH managing-director Mark Sullivan said the Ghana FDA approval was the "first registration of moxidectin in a country disproportionately affected by neglected tropical diseases".

"This is a new model, it is the first time a not-for-profit company has achieved regulatory approval and will deliver a completely novel medicine into an endemic country without the involvement of a multi-national pharmaceutical company or generic company partner," Mr Sullivan said. "Ghana has shown leadership in the evaluation of moxidectin and we have been delighted to support them," Mr Sullivan said.

MDGH vice president and project leader Sally Kinrade said the approval was "the culmination of more than 25 years in the development of moxidectin for the treatment of river blindness and other human diseases".

"It is fitting that Ghanaian communities will be the first to benefit from the implementation of moxidectin to help progress their disease elimination goals given that the first study of moxidectin in infected people was conducted in Ghana," Ms Kinrade said.

Medicines Development for Global Health is a not-for-profit organization.

## STANDARD AND POOR'S DOW JONES INDICES

Standard & Poor's says it has promoted Clarity to the ASX200 and Echo IQ to the All Technology Index, effective from December 23, 2024.

Previously, Standard and Poor's has told Biotech Daily that inclusion in the indices is based solely on market capitalization.

The Biotech Daily Top 40 Index (BDI-40) is based on quality of science, benefit to human health, board and management, investment potential and market capitalization.

## PARADIGM BIOPHARMACEUTICALS

Paradigm says it has raised $16 million at 40 cents a share and the Therapeutic Goods Administration agrees a phase III trial will be sufficient for full PPS registration.

Paradigm said it had "firm commitments" to raise the $16 million to fund its phase III trial of pentosan poly-sulfate sodium (PPS) for knee osteoarthritis.

The company said the issue price was a 2.9 percent premium to the 30-day volume weighted average.

Paradigm said it would issue one "loyalty" option for every four shares held by shareholders at the "late January 2025" record date, exercisable at 65 cents each within 12 months; and shareholders would receive an additional piggyback option per two loyalty options exercised, exercisable at $1.00 each within 24 months from the date of expiry of the loyalty options.

Paradigm said the loyalty option program could raise up-to an additional $63.3 million from shareholders "by early 2026".

The company said it would use $5.5 million of the funds raised to set up its phase III trial in Australia and the US, $6.1 million for site recruitment, $1.5 million for manufacturing and inventory as well as $2.9 million for new drug application-enabling studies and working capital.

Paradigm said that Bell Potter Securities was lead manager and bookrunner to the placement, with Blue Ocean Equities acting as co-manager.

In November, the company said the US Food and Drug Administration approved a 466-patient, phase III trial of injectable PPS for knee osteo-arthritis (BD: Nov 28, 2024).

Today, Paradigm said the Australian Therapeutic Goods Administration (TGA) agreed that the "proposed phase III [osteo-arthritis] program, if successfully executed, will provide the necessary evidence to support full registration of PPS in Australia".

The company said that the TGA acknowledged "that preliminary clinical results for PPS showed benefits that could be clinically meaningful to patients suffering from moderate to severe osteoarthritis of the knee".

Paradigm said the TGA "noted that for patients with minor or mild osteoarthritis this is not considered seriously debilitating" and concluded the data supported the registration of PPS "through the traditional registration pathway rather than via a provisional determination application".

Paradigm fell 4.5 cents or 7.8 percent to 53.5 cents with 7.4 million shares traded.

## NYRADA

Nyrada says its share purchase plan at 12.0 cents per Chess depository interest has raised $85,000 of a hoped-for $1,000,000.

In October, Nyrada said it had raised $3.36 million in a placement at 12 cents per CDI, with a $1.0 million purchase plan to follow (BD: Oct 28, 2024).

Nyrada was up half a cent or 4.55 percent to 11.5 cents.

## RECCE PHARMACEUTICALS

Recce says it has Indonesian Drug and Food Regulatory Authority approval to begin its up-to 300-patient, phase III trial of R327 topical gel for diabetic foot infections.
Last month, Recce said it had ethics approval to start the phase III, double-blinded, placebo-controlled trial of R327 topical gel for diabetic foot infections in Indonesia, with the first patients expected to be enrolled by “mid-December” (BD: Nov 11, 2024).
Today, the company said with both approvals secured it remained “on track to commence the registrational phase III clinical trial” by 2025.
Recce said the trial would run for about 12 months, with “an expected read-out in late 2025 and expected regulatory approval and commercial launch in 2026”.
Recce chief executive officer James Graham said the approval was “a significant achievement, bringing Recce closer to commercialization and profitability”.
Recce was up 1.5 cents or 3.2 percent to 48.5 cents.

## BTC HEALTH

BTC says it will run the London-based heart valve and medical device company Corcym’s Australia and New Zealand operations, for an expected $3.6 million a year.
BTC said it had an exclusive distribution and supply partnership with Corcym, effective from January 1, 2025, subject to standard conditions, with subsidiary BTC Cardio assuming “responsibility for the operations of Corcym’s established Australia/New Zealand business, delivering a material increase to its revenue base”.
BTC said Corcym provided its reimbursed heart valve products to more than 60 public and private hospitals in Australia and New Zealand and that it would acquire Corcym’s current inventory and offer to employ Corcym’s regional sales team.
The company said Corcym’s products included the Perceval Plus sutureless aortic tissue valve, Carbomedics mechanical heart valves for aortic and mitral valve replacement and Memo 4-Dimensional mitral valve rings.
BTC said it would fund the $2.6 million additional cost of running the Corcym business with its cash reserves and a $2 million loan from the Commonwealth Bank of Australia.
BTC executive chair Dr Richard Treagus said the partnership was “another significant milestone in BTC Health's growth strategy and is profit accretive immediately”.
“It is a real opportunity to broaden BTC Cardio's product offering and access to cardiothoracic surgical units,” Dr Treagus said.
BTC was up 0.1 cents or 1.7 percent to six cents.

## CAMBIUM BIO (FORMERLY REGENEUS)

Cambium says it has US Food and Drug Administration fast track designation for its Elate Ocular, or CAM-101 for the treatment of dry eye disease.
Earlier this year, the then Regeneus said it merged with the Atlanta, Georgia-based Cambium Medical Technologies for its Elate Ocular for dry eye disease in exchange for shares and 5.5 percent of future royalties (BD: Feb 14, Apr 5, 8, 2024).
Today, the company said the designation would “facilitate the development and expedite the review of drugs that treat serious conditions and address unmet medical needs”.
Cambium said that the status enabled “more frequent interactions with the FDA throughout the drug development process and makes Elate Ocular eligible for potential accelerated approval and priority review”.
Cambium said the approval supported the opening of two, phase III trials by July 2025.
Cambium fell one cent or 1.6 percent to 61.5 cents.

## FIVEPHUSION

Fivephusion says it has an “exclusive option” to develop the University of Wollongong’s Resectassist implantable drug delivery system for solid tumors.

Fivephusion said the single-use, drug-eluting, bio-degradable Resectassist implant allowed for the “targeted administration of a diverse range of approved and investigational drugs directly into solid tumors with high unmet medical needs”.

The company said using standard endoscopy procedures, the lead candidate Resectassist-Folfirinox (folinic acid, fluorouracil, irinotecan and oxaliplatin) was designed to deliver “high-dose Folirinox chemotherapy directly into [locally advanced pancreatic cancer] tumors”.

Fivephusion said Resectassist delivery system led to a “substantially safer, more tolerable and significantly more efficacious treatment”.

The company did not disclose the commercial terms of the agreement.

Fivephusion said Resectassist was “designed to deliver a diverse range of other drug payloads, including hydrophobic and hydrophilic compounds, biologics, peptides and mRNA therapeutics”.

Fivephusion managing-director Dr Christian Toouli said the transaction formalized “a long-term collaboration with the University of Wollongong to secure an exciting pipeline development opportunity that will ultimately follow the development and commercialization of Deflexifol”.

Earlier this year, Fivephusion said it had ethics approval for an up-to 50-patient, phase Ib trial to study its Deflexifol “potential of hydrogen formulation” for administering 5-fluorouracil chemotherapy as a first-line treatment for unresectable metastatic colorectal cancer (BD: Apr 9, 2024).

“We are looking forward to rapidly developing the Resectassist platform into a clinical trial program to optimize treatment for cancer patients,” Dr Toouli said.

Fivephusion is a private company.

## ECHO IQ

Echo IQ says Echosolv for aortic stenosis will be reimbursed under miscellaneous CPT code 93799 at a rate of $US100 ($A157) to $US150 ($A235).

Echo IQ said that the CPT code reimbursed the use of Echosolv on a fee-per-use basis and that the rate was an increase on the previously expected $US68.

The company said it expected to receive between 30 percent and 60 percent of the total reimbursement rate, with hospitals and clinics to work directly with payers to use the code and seek reimbursement for the use of its technology.

Echo IQ said it would continue to work towards obtaining full reimbursement and had begun the process of filing for a category III CPT code, which would “create a code for utilization of Echosolv as a new or emerging technology and marks an important step in progress towards a designated CPT code”.

The company said it expected a category III CPT code application to be filed “in February 2025 and anticipates approval by mid-2025”.

Echo IQ chief executive officer Dustin Haines said the code was “a very important first step in our pathway towards broader reimbursement … in the early stages of 2025”.

“These developments progress Echo IQ toward gaining first revenues in the US, while also highlighting proof-of-concept of the technology and delivering measurable improvements to the screening of [aortic stenosis] and potential enhancements to patient outcomes,” Mr Haines said.

Echo IQ was up one cent or 3.85 percent to 27 cents with 11.3 million shares traded.

## CYCLOPHARM

Cyclopharm says a 74-patient, independent study shows its Technegas lung imaging device is effective and efficient in planning lung transplant surgeries.

Last year, Cyclopharm said the US Food and Drug Administration had approved Technegas for pulmonary embolism imaging (BD: Oct 2, 2023)

Today, the company said a study conducted by Washington University's Mallinckrodt Institute of Radiology in St Louis Missouri, compared Technegas to the current US standard ventilation imaging 133-Xenon.

Cyclopharm said the study showed that Technegas "achieved a high correlation with Xenon in quantifying relative lung ventilation" and confirmed clinical equivalence.

The company said that the results showed that "Technegas outperformed Xenon in cases involving obstructive lung disease, due to its superior peripheral deposition and image quality".

Cyclopharm said Technegas was shown to be safer and more accessible for hospitals and avoided "the logistical complexities of radioactive gas handling associated with Xenon".

The company said Technegas was positioned as "a pivotal tool for pre-operative planning in lung transplantation and other thoracic surgeries, improving patient outcomes through accurate lung function assessment".

Cyclopharm said the study, titled 'Comparability of Quantifying Relative Lung Ventilation with Inhaled 99mTc-Technegas and 133Xe in Patients Undergoing Pre-lung Transplant Evaluation' was published in the US Journal of Nuclear Medicine and available at: https://bit.ly/4f73fzg.

Cyclopharm managing-director James McBrayer said the "study, wholly-driven by clinicians, clearly illustrates the transformative potential of Technegas across the US healthcare market".

"By validating its clinical equivalence to Xenon and highlighting its operational benefits, this independent research paves the way for broad adoption of Technegas across a range of respiratory conditions in the world's largest healthcare market," Mr McBrayer said.

Cyclopharm was up six cents or 3.7 percent to $1.67.

## ACTINOGEN MEDICAL

Actinogen says it has treated the first US patient in its 220-patient, phase IIb/III trial of Xanamem 10mg oral tablet for mild-to-moderate Alzheimer's disease.

Earlier this year, Actinogen said it had treated the first of 220-patients in the phase IIb trial of its Xanamem cortisol synthesis inhibitor (BD: Apr 15, 2024).

Today, the company said it had opened 10 clinical sites in the US in addition to the existing 15 Australian sites, with screening and enrolment expected to quicken and "deliver interim results next year and final results in 2026".

Actinogen said interim analysis was expected by October 2025 when about 100 patients had reached 24 weeks of treatment.

Actinogen managing-director Dr Steven Gourlay said "the 10 new sites in the US will bolster the already active recruitment from our Australian sites."

"Based on the encouraging safety and clinical activity seen in multiple prior trials of Xanamem in both [Alzheimer's disease] and major depressive disorder, we are confident that the trial will confirm clinically and statistically meaningful results," Dr Gourlay said.

Actinogen was unchanged at 3.1 cents with 14 million shares traded.

BLINKLAB

Blinklab says it will release 4,150,022 shares from ASX escrow on December 14, 2024.
According to its most recent notice, Blinklab had 57,086,135 shares on offer, meaning that following the release from escrow it would have 61,236,157 shares available for trading and 37,913,846 shares remaining in ASX escrow.
Blinklab was up half a cent or 1.9 percent to 27 cents.