# Biotech Daily

Thursday July 25, 2024

*Daily news on ASX-listed biotechnology companies*

*** ASX, BIOTECH DOWN: AMPLIA UP 61%; MESOBLAST DOWN 8%**

*** AMPLIA: '3 AMP945 PANCREATIC CANCER PARTIAL RESPONSES'**

*** TISSUE REPAIR: TGA APPROVES GLUCOPRIME TR PRO+ WOUND GEL**

*** ONCOSIL RAISES $2.7m FROM UNNAMED INSTITUTION**

*** MEDADVISOR RECORD RECEIPTS UP 13% TO $118m**

*** NEXT SCIENCE H1 RECEIPTS UP 25% TO $17m**

*** MICROBA RECEIPTS UP 94% TO $12m**

*** ATOMO RECEIPTS UP 15% TO $3.8m**

*** MAYNE FILES SUN PHARMA IMVEXXY PATENT CASE**

*** CERTA WINS EU FT011 FOR SCLEROSIS ORPHAN STATUS**

*** CARTHERICS LICENCES STEM CELLS TO UNIQUEST, SYDNEY UNI**

*** FIRST SENTIER REDUCES TO 5.9% OF NANOSONICS**

*** BIO-MELBOURNE: 'BENCH TO BEDSIDE' RADIO-THERAPY FORUM**

## MARKET REPORT

The Australian stock market fell 1.29 percent on Thursday July 25, 2024, with the ASX200 down 102.5 points to 7,861.2 points. Ten of the Biotech Daily Top 40 stocks were up, 18 were down, 11 traded unchanged and one was untraded. All three Big Caps were down.

Amplia was the best, up 3.8 cents or 61.3 percent to 10 cents, with 4.7 million shares traded. Alcidion climbed 10.6 percent; Syntara was up 7.9 percent; Universal Biosensors rose 6.9 percent; Immutep improved 4.7 percent; Resonance and Telix rose two percent; Medadvisor and Micro-X were up more than one percent; with Emvision up by 0.5 percent.

Mesoblast led the falls, down 10.5 cents or 8.4 percent to $1.15, with 10.1 million shares traded. Paradigm lost seven percent; SDI was down 6.4 percent; Percheron shed 5.1 percent; Nanosonics and Polynovo fell more than four percent; Dimerix and Neuren were down three percent or more; Avita, Clarity and Cochlear shed more than two percent; 4D Medical, Compumedics, CSL, Genetic Signatures, Imugene, Orthocell, Pro Medicus, Proteomics and Resmed were down one percent or more; with Clinuvel down 0.8 percent.

## AMPLIA THERAPEUTICS

Amplia says three of six patients in its phase IIa trial of narmafotinib, or AMP945, for advanced pancreatic cancer “have recorded a confirmed partial response”.
Earlier this year, Amplia said it had dosed the first of up-to 50 patients in the trial of narmafotinib with chemotherapy for pancreatic cancer (BD: Jan 21, 2024).
In July, the company said it had enrolled all 26 patients in the first stage of the two-stage trial of narmafotinib for pancreatic cancer (BD: Jul 3, 2024).
Today, Amplia said ‘confirmed partial response’ meant there was “at least a 30 percent decrease in the overall size of tumor lesions, and no new tumor lesions, in these patients sustained over a two-month period”.
The company said of the six patients currently assessed at four-months, in addition to the three confirmed partial responses, two patients had sustained stable disease.
Amplia said once six patients had confirmed partial or complete responses an additional 24 patients would be enrolled, giving a total of 50 patients for the trial.
Amplia managing-director Dr Chris Burns said that “to be reporting that three confirmed partial responses have been observed so early in this stage of the trial is extremely encouraging”.
“We are well on track to reach the efficacy threshold of six confirmed partial or complete responses by [October 2024], which will then allow us to restart the trial to recruit the full cohort of 50 patients,” Dr Burns said.
Amplia was up 3.8 cents or 61.3 percent to 10 cents with 4.7 million shares traded.

## TISSUE REPAIR

Tissue Repair says the Australian Therapeutic Goods Administration has approved its yeast-based Glucoprime TR Pro+ gel for wound-healing.
In 2021, at the time of its initial public offer to raise $22 million at a $1.15 a share, Tissue Repair said that the active ingredient of its topical treatment for wound repair TR Pro+, then called TR987, was Glucoprime, invented by former Novogen and Noxopharm chief executive officer Prof Graham Kelly (BD: Nov 24, 2021).
Today, the company said the product had been approved to be sold in 3g sachets as well as 10g and 50g tubes.
Tissue Repair said it launched TR Pro+ in June 2023 and the product was “a new standard in the aftercare of medical and aesthetic procedures”.
The company said the TGA approval would allow it “to promote its considerable scientific and clinical data more broadly”.
Tissue Repair said “securing general claims around skin healing, repair and regeneration will allow the company to significantly expand the indications that it can market the product for including acute wounds, and a broad range of derm conditions”.
The company said that despite the product’s current regulatory status as a cosmetic, TR Pro+ sales in June were a record high with revenue for the three months to March 31, 2024 up 130 percent on the prior period and increasing to more than 160 clinics.
Tissue repair said that its short-term focus was on increasing growing distribution.
The company said that it would provide “a broader more detailed update presentation from its co-founder and executive director Tony Charara in relation to this significant development and the Company’s broader strategies in the immediate commercialization of its proprietary technology as well as the imminent commencement of [US] phase III clinical trials for its advanced wound drug candidate TR987.
Tissue Repair was up 21 cents or 95.45 percent to 43 cents with 5.3 million shares traded.

## ONCOSIL MEDICAL

Oncosil says it has raised $2.7 million at 0.7 cents a share in a placement to an unnamed "Australian institutional investor".

Oncosil said the investor would receive one short-dated listed option for every share bought, exercisable at 0.9 cents each by June 20, 2025, and would hold 11.4 percent of the company following the issue of shares.

The company said the offer price was a 22 percent discount to both the five-day volume weighted average price and the last closing price on July 24, 2024.

Oncosil said the funds would be used for commercialization and regulatory approval for its pancreatic cancer radiation device, manufacturing and supply chain optimization, validation of its Macquarie Park facility, clinical trials to expand approval of the current label of its device and for general working capital purposes.

The company said Forrest Capital and McFarlane Cameron were joint lead managers to the placement.

Oncosil was unchanged at 0.9 cents with 2.8 million shares traded.

## MEDADVISOR

Medadvisor says it has record customer receipts for the year to June 30, 2024, up 13.0 percent to $118,058,000, compared to the previous corresponding period.

Medadvisor said that customer receipts from contracts for its patient medication management platform with pharmacies were up 32.7 percent in the three months to June 30, 2024 to $22,719,000, compared to the prior corresponding period.

Medadvisor managing-director Rick Ratliff said the strong performance in the three months to June 30, 2024 in both the US and Australia capped "off a record year for Medadvisor".

"US growth through the quarter was driven by increased demand for patient engagement programs powered by our platform, Thriv," Mr Ratliff said.

"In addition, the overall number of patient engagement programs increased by 20 percent over the prior corresponding period," Mr Ratliff said.

The company said it had a cash burn of $3,567,000 for the three months to June 30, with cash and equivalents of $15,578,000 at June 30, 2024 compared to $14,199,000 at June 30, 2023.

Medadvisor was up one cent or 1.9 percent to 54 cents.

## NEXT SCIENCE

Next Science says customers receipts for the six months to June 30, 2024 was up 25.0 percent to $US11,432,000 ($A17,477,000) on the prior corresponding period.

Next Science said that receipts from customers from sales of its products for biofilm-based infections including Xperience and Blastx for wound care were up 13.1 percent for the three months to June 30, 2024 to $US6,026,000, compared to the previous corresponding period.

The company said the increase in product sales was a result of higher direct sales of Xperience and partner sales, which offset a decline in the durable medical equipment channel due to changes in its go-to-market strategy.

Next Science said it had cash burn of $US1,310,000 for the three months.

The company said it had cash and cash equivalents of $US3,572,000 at June 30, 2024 compared to $US3,483,000 at June 30, 2023.

Next Science was unchanged at 29 cents.

## MICROBA LIFE SCIENCES

Microba says that receipts from customers for the year to June 30, 2024 were up 94.4 percent to $12,319,000, compared to the previous corresponding period.
Microba said customer receipts from sales of its gastro-intestinal disorder test Metaxplore and sales of the recently acquired Invivo Clinical's microbiome tests for the three months to June 30, 2024 were up 175.6 percent to $4,658,000.
Last year, the company said it had completed its up-to $21.2 million acquisition of the Gloucestershire, England-based Invivo Clinical, a microbiome testing business with products including vaginal, oral and urinary testing (BD: Dec 5, 2024).
Today, Microba said $2.21 million of its customer receipts for the three months to June 30, 2024 were from sales of its Invivo products, with $4.45 million from Invivo sales for the six months FROM December to June 30, 2024.
The company said it had a cash burn of $2,280,000 for the three months to June 30, 2024.
Microba said it had cash and cash equivalents of $20,890,000 at June 30, 2024 compared to $32,044,000 at June 30, 2023.
Microba was up 1.5 cents or 8.3 percent to 19.5 cents.

## ATOMO DIAGNOSTICS

Atomo says receipts from customers for the year to June 30, 2024 was up 15.3 percent to $3,807,000, compared to the prior corresponding period.
Atomo said that receipts from customers for its HIV self-tests, the Lumos Febridx tests for respiratory diseases and the Pascal blood-based Burnet Institute syphilis test for the three months to June 30, 2024 were up 181.7 percent to $1,079,000.
The company said it had unaudited revenue for the three months of $1.64 million, with $1.4 million from sales of its HIV test and $234,000 from Pascal sales.
Atomo said it had a cash burn of $1,494,000 for the three months to June 30, 2024.
The company said it had cash and cash equivalents of $3,688,000 at June 30, 2024 compared to $6,470,000 at June 30, 2023.
Atomo was unchanged at 2.5 cents.

## MAYNE PHARMA GROUP

Mayne Pharma says it has filed a patent infringement lawsuit against Sun Pharmaceutical Industries Ltd in the US District Court for the District of New Jersey.
Mayne said its suit alleged "infringement by Sun Pharma of all 20 Orange Book listed patents relating to [its] Imvexxy, estradiol vaginal inserts".
The company said the lawsuit followed Sun Pharma's submission of "an abbreviated new drug application to the US Food and Drug Administration seeking approval to market a generic version of Imvexxy, including a paragraph IV certification challenging [its] Orange Book listed patents".
Mayne said the lawsuit formally started the legal process, triggering "a 30-month stay of any potential FDA approval for Sun Pharma's [abbreviated new drug application]".
Mayne Pharma chief executive officer Shawn O'Brien said the lawsuit reflected the company's "commitment to protecting our intellectual property rights".
"As one of the top two specialized women's healthcare companies in the US, intellectual property is important to our business, and we are confident in our ability to vigorously defend the Imvexxy franchise for the benefit of our patients," Mr O'Brien said.
Mayne Pharma fell 16 cents or 3.5 percent to $4.36.

## CERTA THERAPEUTICS

Certa says the European Medicines Agency has granted orphan drug designation for its oral FT011 as a treatment for systemic sclerosis.

Earlier this year, Certa said it had US Food and Drug Administration (FDA) fast-track designation for FT011, following orphan drug designation (BD: Feb 20, 2024).

Today, the company said orphan drug designation provided benefits including the potential for extensive marketing exclusivity following regulatory approval, reduction in regulatory fees and, in the case of EU, a centralized approval process.

Certa said its FT011 was a novel, first-in-class oral therapy for the treatment of chronic fibrosis in multiple organs and it targeted the membrane GPCR receptor GPR68, which it called “a master switch of fibrosis”.

The company said “an extensive body of data demonstrates promising efficacy in multiple in vitro and in vivo models of inflammatory and fibrotic disease” and last year, it said a 30-patient, phase II trial showed 400mg of FT011 led to a “clinically meaningful improvement” in 60 percent of systemic scleroderma patients ($p = 0.019$) (BD: Nov 16, 2023).

Today, Certa said systemic sclerosis was “a chronic, progressive, autoimmune disease characterized by inflammation and fibrosis in the skin and in various internal organs, commonly lungs, kidneys and heart … [with] no treatments on the market that effectively stop or reverse scarring in the skin and organs”.

The company said it was planning a phase IIb confirmatory systemic sclerosis clinical trial with FT011 and was developing biomarkers and gene signatures to identify patients most likely to respond to treatment.

Certa chief executive officer Prof Darren Kelly said GPR68 inhibition modulated the pathways causing inflammation and fibrosis to the skin in systemic sclerosis patients.

“With limited treatment options available for patients with [systemic sclerosis], the [European Medicines Agency] orphan drug designation and FDA orphan drug and fast track designations reflect the potential for FT011 to address a critical need for people living with this debilitating and life-threatening condition,” Prof Kelly said.

Certa is a private company.

## CARTHERICS PTY LTD

Cartherics says it will licence its stem cell-derived cardio-myocytes for cardiovascular disease for research by the University of Queensland and the University of Sydney.

Cartherics said that the University of Queensland’s Uniquest and the University of Sydney would commercialize any induced pluripotent stem cell (IPSC)-derived cardiomyocyte products developed by their research.

The company said it would have access to any technologies developed for use “outside the field of cardiovascular disease”.

Cartherics said a reciprocal revenue sharing arrangement applied to products “developed and commercialized from the IPSC line in the field of cardiovascular disease and for products outside the field, respectively”.

The company said the research would develop IPSC-derived cardio-myocytes for cardiovascular diseases under a $4.9 million grant from the Federal Government’s Medical Research Future Fund.

Cartherics said the research would be led by the University of Sydney’s Prof James Chong and Prof Peter Gray at the University of Queensland’s Australian Institute for Bioengineering and Nanotechnology (AIBN).

Cartherics is a private company.

## NANOSONICS

First Sentier Investors Holdings Pty Ltd says it has reduced its shareholding in Nanosonics from 20,940,035 shares (6.91%) to 17,829,015 shares (5.88%)
The Sydney-based First Sentier said that between March 1 and July 19, 2024 it bought and sold shares in more than 50 transactions, with the single-largest sale on June 20 of 242,937 shares for $728,811, or $3.00 a share.
Nanosonics fell 14 cents or 4.5 percent to $2.97 with 900,493 shares traded.

## BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says it will hold its forum on advancing radio-therapies and radio-pharmaceuticals for cancer diagnosis on August 14, 2024.
The Bio-Melbourne Network said the event, titled 'Bio-Forum - From Bench to Bedside: Advancing Radiopharmaceuticals in Victoria' would include speakers from Telix, the Peter MacCallum Cancer Centre and Cyclotek Pty Ltd, on the manufacture of radio-pharmaceuticals for clinical trials and research and development.
The industry organization said in-person tickets were $85 for members and $175 for non-members, with online registration costing $25 for members and $45 for non-members.
The Network said the event would be held online and at the Thornbury Room, Stamford Plaza Melbourne, 111 Little Collins Street, Melbourne, on August 14, 2024, from 8am to 11am (AEST).
Information and registration are available at: https://bit.ly/4d7befi.