Biotech Daily

Monday January 20, 2025

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: NANOSONICS UP 6%; DIMERIX DOWN 8%**

*** COGSTATE UNAUDITED H1 REVENUE UP 18% TO $38.5m**

*** CLINUVEL: 'SCENESSE RE-PIGMENTS SKIN IN 4 VITILIGO PATIENTS'**

*** AMPLIA: 'NARMAFOTINIB 400mg DOSE FOR PANCREATIC TUMORS'**

*** EBR FDA FACTORY INSPECTION OK; EXPEDITED REIMBURSEMENT**

*** PYC VP-001 FOR RP11 WINS FDA RARE PAEDIATRIC DISEASE STATUS**

*** GENETIC TECHNOLOGIES DISCLOSES $525k ENDEAVOR DNA SALE**

*** ORTHOCELL RECEIVES $3.2m FEDERAL R&D TAX INCENTIVE**

*** EMVISION RECEIVES $2.1m FEDERAL R&D TAX INCENTIVE**

*** INVEX RECEIVES $220k UK R&D TAX INCENTIVE**

*** MERCER INVESTMENTS TAKES 5% OF MEDADVISOR**

*** SOMNOMED APPOINTS ANDREW PRICE DIRECTOR**

MARKET REPORT

The Australian stock market was up 0.45 percent on Monday January 20, 2025, with the ASX200 up 37.0 points to 8,347.4 points. Eleven of the Biotech Daily Top 40 companies were up, 16 fell, 12 traded unchanged and one was untraded.

Nanosonics was the best, up 21 cents or 6.3 percent to $3.53, with 768,400 shares traded; followed by Micro-X and EBR, up 6.25 percent and 6.1 percent, respectively, to 8.5 cents and $1.575, respectively. Mesoblast, Opthea, Pro Medicus and Proteomics climbed more than three percent; Imugene rose 2.5 percent; Avita, Cochlear, Impedimed, Paradigm and Resmed were up more than one percent; with Aroa up by 0.7 percent.

Dimerix led the falls, down 4.5 cents or 8.4 percent to 49 cents, with 7.8 million shares traded; followed by Starpharma, down 8.3 percent to 11 cents, with 591,259 shares traded. Medical Developments lost seven percent; 4D Medical and Orthocell shed more than six percent; Medadvisor and SDI fell more than four percent; Amplia and Clarity were down more than three percent; Cynata and Neuren shed more than two percent; Clinuvel, Immutep and Telix were down more than one percent; with CSL, Cyclopharm and Polynovo down by less than one percent.

COGSTATE

Cogstate says revenue for the six months to December 31, 2024 was up 18.3 percent to $US23.9 million ($A38.5 million), compared to the previous corresponding period.
Cogstate said that the increased unaudited revenue was driven by a 26.8 percent rise in its clinical trials services business from $US17.9 million in the prior corresponding period to about $US22.7 million in the six months to December 31, 2024.
The company said $US14.2 million of revenue was from contracts for clinical trials of Alzheimer's disease and the remaining $US6.1 million in other indications.
Cogstate said revenue from its healthcare business was $US1.2 million, down 45.45 percent due to an amendment to its agreement with Eisai.
Last year, Cogstate said that it had amended its licence with Tokyo's Eisai Co Ltd to re-acquire the rights to its products in exchange for a $15 million reduction in future royalties (BD: Apr 2, 2024).
Today, the company said that it expected gross profit margin and earnings before interest and taxation (Ebit) "to be consistent" with the six months to June 30, 2024.
Cogstate said that it had unaudited cash and cash equivalents of $US34.23 million at December 31, 2024, compared to $US25.3 million at December 31, 2023.
Cogstate said that its audited six-month results would be released on February 20, 2025.
Cogstate was up four cents or 3.6 percent to $1.15.

CLINUVEL PHARMACEUTICALS

Clinuvel says four patients in its 'CUV105' trial of afamelanotide 16mg, or Scenesse, have had white vitiligo patches re-pigmented and total darkening of unaffected skin.
In 2023, Clinuvel said it had dosed the first of up-to 200-patients in its open-label, randomized, phase III trial of Scenesse for vitiligo, or de-pigmented skin, and it expected recruitment to be completed in about "12 months, depending on the centre's ability to identify suitable patients" (BD: Oct 18, 2023).
Last year, the company said it extended recruitment for the phase III CUV105 trial, of Scenesse and had relaxed the inclusion criteria due to enrolment and patient retention rates (BD: Aug 21, 2024).
Today, Clinuvel said the results were from four long-term case studies of patients in the trial with widespread vitiligo, including face, head and neck involvement, that had Fitzpatrick skin type IV and had received seven Scenesse implants, each, as well as up-to 53 administrations of standard-of-care narrowband ultra-violet B photo-therapy.
The company said two cases showed "re-pigmentation of white vitiligo patches occurred after completion of treatment".
Clinuvel said "two patients previously unresponsive to [ultra-violet B photo-therapy] responded to the afamelanotide and [photo-therapy] treatment".
The company said follicular pigmentary response was "seen within the vitiligo patches after four weeks of starting the treatment with afamelanotide".
Clinuvel said the drug as an adjunct to narrowband ultra-violet B photo-therapy was well tolerated and that patients' reports thus far were "excellent, in that all four patients have been excited about the results obtained".
The company said those patients who had initially received ultra-violet B photo-therapy alone and continued on to receive afamelanotide as adjunct to photo-therapy were "content to stay in the trial".
Clinuvel said physicians were "satisfied with the results seen to date".
Clinuvel fell 18 cents or 1.5 percent to $11.70 with 105,604 shares traded.

AMPLIA THERAPEUTICS

Amplia says further data from its 14-patient, phase Ib trial of oral narmafotinib for pancreatic cancer shows “a dose-dependent reduction in tumor size”.

In 2023, Amplia said its 14-patient phase Ib trial of 100mg, 200mg and 400mg of narmafotinib, then AMP945, for pancreatic cancer with standard-of-care showed it was safe and well-tolerated with “very encouraging” activity (BD: Oct 30, 2023).

Today, the company said further analysis showed that “patients on the 400mg dose of narmafotinib had an average treatment duration of 8.3 months, significantly better than historical data for patients receiving chemotherapy alone”.

Amplia said that the additional data was presented at a Keystone meeting held in Banff, Alberta from January 18 to 21, 2025.

The company said the presentation included additional pre-clinical data from studies of mice which showed narmafotinib had “anti-fibrotic effects in a mouse model of pancreatic cancer and that narmafotinib has a single-agent activity in this model”.

Amplia said the pre-clinical data showed that narmafotinib enhanced “the activity of chemotherapy and appears to inhibit resistance to the chemotherapy that develops over time, in the mouse model”.

Amplia managing-director Dr Chris Burns said the company was “delighted to present further data about our drug narmafotinib and its activity in the … clinical trial”.

“Demonstration of the drug’s activity in cancer patients, as well as in defined animal models of cancer, helps to build a robust dataset that underpins the commercial potential of the drug,” Dr Burns said.

Amplia fell 0.3 cents or 3.6 percent to 8.1 cents with 1.4 million shares traded.

EBR SYSTEMS

EBR says the US Food and Drug Administration manufacturing inspection has been completed and its Wise system has been accepted for expedited reimbursement.

Last year, EBR said it completed its 100-day meeting with the FDA for its Wise wireless pacemaker and “approval timing remains on track” (BD: Jan 19, 2025).

Today, the company said the FDA had completed its inspection “with no observations”, meaning its pre-market approval submission was in its final phase, and it expected regulatory approval on or before April 13, 2024, with commercial launch by 2026.

EBR said its Wise system had been accepted into the US Centers for Medicare and Medicaid Services’ (CMS) “new and highly selective transitional coverage for emerging technologies (TCET) reimbursement pathway”.

The company said acceptance into the pathway provided it with early engagement with Medicare and expedited coverage, including transitional coverage of up-to five years.

EBR said the Centers for Medicare and Medicaid Services had “indicated that they expect to only accept five new technologies each year into the pathway”.

EBR chief executive officer John McCutcheon said the company was “very pleased with the successful conclusion of the FDA’s pre-approval inspection audit”.

“These audits are very rigorous, and the result is a clear indication of our team’s commitment to following good manufacturing practices,” Mr McCutcheon said.

“EBR is honored that Wise is one of the first five technologies that CMS indicated will be approved to participate in the inaugural year of the CMS TCET pathway,” Mr McCutcheon said. “This is a new program that provides a faster path to a national coverage decision for medical devices that have the FDA breakthrough device designation status.”

EBR was up nine cents or 6.1 percent to $1.575 with 1.6 million shares traded.

PYC THERAPEUTICS

PYC says it has rare paediatric disease designation from the US Food and Drug Administration for VP-001 as a treatment for retinitis pigmentosa type 11 (RP11).
PYC said the status aimed to “incentivize drug development for serious and rare diseases affecting children”.
According to the FDA’s website, under the rare pediatric disease program a sponsor who receives an approval for a drug or biological product for a rare pediatric disease “may qualify for a voucher that can be redeemed to receive priority review for a different product”.
The FDA website said that the “sponsor may also transfer or sell the voucher to another sponsor”.
PYC fell two cents or 1.7 percent to $1.14 with 1.5 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies administrators say they sold the Easy DNA and Affinity DNA direct-to-consumer businesses for $525,000 to the El Paso, Texas-based Endeavor DNA Inc.
Last week, the administrators said they would sell teh direct-to-consumer businesses but did not disclose the sale price nor the buyer (BD: Nov 20, 2024; Jan 19, 2025).
Today, the company said Endeavor purchased the businesses in cash and that it had given Endeavor "the option to purchase all of the shares in each of its two subsidiaries that employ staff involved in the conduct of the businesses for a nominal value”, within four weeks of the sale’s completion.
Genetic Technologies was in a suspension and last traded at 3.9 cents.

ORTHOCELL

Orthocell says it has received $3,185,026 from the Australian Taxation Office under the Federal Government’s Research and Development Tax Incentive program.
Orthocell said the incentive related to expenditure for the year to June 30, 2024.
Orthocell fell nine cents or 6.6 percent to $1.28 with 1.9 million shares traded.

EMVISION MEDICAL DEVICES

Emvision says it has received $2,120,568 from the Australian Taxation Office under the Federal Government’s Research and Development Tax Incentive program.
Emvision said the incentive related to expenditure for the year to June 30, 2024.
The company said additional research and development costs incurred during the year to June 30, 2024 were capitalized for tax purposes and were expected to be eligible expenditure for rebate in subsequent tax incentive claims.
Emvision was unchanged at $1.83.

INVEX THERAPEUTICS

Invex says it has received GBP144,000 ($A220,000) from the UK Government as a research and development tax incentive for the year to June 30, 2024.
Last year, Invex said its UK research and development tax rebate of GBP633,000 was delayed with “no certainty as to the timing of receipt of funds” due to changes to processing claims by the UK Revenue and Customers Office (BD: Mar 5, 2024).
Invex was untraded at 7.2 cents.

MEDADVISOR

Melbourne's Mercer Investments (Australia) Ltd says it has become a substantial shareholder in Medadvisor with 27,790,619 shares, or 5.035%.
Mercer Investments said that between September 27, 2024 and January 15, 2025 it bought shares at prices ranging from 20.0 cents to 42.31 cents a share and sold shares on September 17 and 24, 2024 for 40.0 cents and 39.75 cents a share, respectively.
Medadvisor fell one cent or 4.65 percent to 20.5 cents with one million shares traded.

SOMNOMED

Somnomed says it appointed Andrew Price as a director on January 17, 2025.
Somnomed said Mr Price was a "seasoned executive in the medical device industry" and had worked for Resmed for 25 years, including as chief supply chain officer as well as roles in product development, project management and business development.
The company said Mr Price held a Bachelor of Design from the University of Technology Sydney.
Somnomed was up 2.5 cents or 5.4 percent to 49 cents.