Biotech Daily

Wednesday April 6, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: MICRO-X UP 5%; PROTEOMICS DOWN 6%**

*** POLYNOVO: RECORD $12m Q3 REVENUE**

*** ALCIDION: $1.4m, 5-YEAR DEAL WITH EAST LANCASHIRE NHS**

*** ZELIRA: DRCN FAILS TO PAY $990k MARIJUANA LICENCE FEE**

*** 4D STARTS XV LUNG SCANS AT PROVIDENCE ST JOSEPH HOSPITAL**

*** AMPLIA READY FOR PHASE II AMP945 PANCREATIC CANCER TRIAL**

*** RACE READY FOR PHASE I ZANTRENE AML, MDS TRIAL**

*** CANN GROUP: GSK $170k TO EVALUATE MARIJUANA SATIPHARM**

*** CORRECTION: AROVELLA**

*** AUSTRALIAN SUPER TAKES 5% OF NANOSONICS**

*** PERENNIAL TAKES 15% OF MICROBA**

*** MICROBA APPOINTS PROF TRENT MUNRO HEAD OF THERAPEUTICS**

*** MEDADVISOR M-D ROBERT READ DROPS CEO ROLE; US CEO WANTED**

MARKET REPORT

The Australian stock market fell 0.5 percent on Wednesday April 6, 2022, with the ASX200 down 37.8 points to 7,490.1 points. Seven of the Biotech Daily Top 40 stocks were up, 22 fell, eight traded unchanged and three were untraded.

Micro-X was the best, up one cent or 4.9 percent to 21.5 cents, with 121,109 shares traded. Patrys and Polynovo climbed more than four percent; Amplia was up 3.6 percent; Genetic Signatures and Oncosil rose more than two percent; with Cochlear and Universal Biosensors up by less than one percent.

Proteomics led the falls, down 7.5 cents or 6.3 percent to $1.115, with 77,177 shares traded. Starpharma lost 5.7 percent; Antisense, Atomo, Imugene and Paradigm fell four percent or more; Actinogen, Immutep and Mesoblast were down three percent or more; Alcidion, Clinuvel and Telix shed more than two percent; Avita, Medical Developments, Neuren, Next Science, Orthocell, Pro Medicus, Resmed and Volpara were down more than one percent; with CSL, Kazia, Nanosonics and Opthea down less than one percent.

POLYNOVO

Polynovo says it has booked record unaudited revenue for the three months to March 31, 2022 up 59.3 percent to $12.26 million compared to the prior corresponding period.
Polynovo said revenue for the nine months to March 31, 2022 was $30.42 million.
Polynovo chair David Williams said more sales representatives "equals a wider geographical footprint and increased sales".
Mr Williams said that more sales representatives along with "the diminishing effects of Covid" have driven record sales in US, the UK, Ireland and Australia.
Polynovo was up five cents or 4.6 percent to $1.13 with 4.8 million shares traded.

ALCIDION

Alcidion says it will receive $1.43m over five years from the UK's East Lancashire Hospitals National Health Service (NHS) Trust, for the implementation of Miya Flow.
Last year, Alcidion said it paid GBP5.3 million for Extramed, a UK provider of patient flow management software with nine UK National Health Service Trusts (BD: Apr 20, 2021).
Today, Alcidion said the agreement was the first upgrade from Extramed's inpatient flow manager to Miya Flow since the acquisition of Extramed.
The company said that Miya Flow would provide clinical specialties with electronic journey boards that show "relevant information at a glance, for the patients in their care".
"This will mean that ward staff, medical staff, dieticians, therapists, pharmacists and a range of specialist clinical teams will have easier visibility of what they need to do to ensure patients … [progress] without delays," Alcidion said.
Alcidion managing-director Kate Quirke said that "patient flow has become an immediate focus for digital technology in healthcare as hospitals aim to improve efficiency at a time of huge demand, and as integrated care systems look to flow systems to help support command and control across their footprint".
Alcidion fell half a cent or 2.5 percent to 19.5 cents with 3.6 million shares traded.

ZELIRA THERAPEUTICS

Zelira says $US750,000 ($A990,000) in licencing fees are overdue from the Camden, Delaware-based DRCN Holdings LLC for its matrix-based cannabinoid capsules.
Last year, Zelira said it had an agreement with DRCN Holdings to licence the matrix-based capsules in return for an upfront, non-refundable, non-contingent licencing fee of $US1 million (BD: Nov 3, 2021).
In January, the company said it had received $US250,000 of the $US1 million fee from DRCN (BD: Jan 10, 2022).
Today, Zelira said that it had been advised the balance would be paid by the end of March, but "despite repeated assurances, both written and verbal, from DRCN and their legal counsel", the fee had not yet been received.
The company said the matrix-based cannabinoid capsules had an "enhanced dissolution profile" and the technology "solves the problem of non-uniformity and separation of cannabinoid from powder bed".
Zelira said it was in discussions with DRCN regarding settlement of the outstanding balance, but was considering all legal options, including termination of the agreement.
The company said that should the agreement be terminated and not proceed, the $US250,000 partial fee received from DRCN would not be refunded and DRCN would not receive access to the capsule technology.
Zelira was unchanged at 1.9 cents with 1.2 million shares traded.

4D MEDICAL

4D says it has begun a clinical pilot program of its XV LVAS lung function scanning system with the Orange, California-based Providence St Joseph Hospital.

4D said St Joseph Hospital was one of 52 hospitals within the Providence Health & Services network and would undertake scans across a range of conditions, with cans for chronic obstructive pulmonary disease and long-Covid already completed.

The company said the XV system had been trailed at Johns Hopkins Medical Center, Cleveland Clinic, Vanderbilt University Medical Center, Duke University Hospital and the University of Miami.

4D chief executive officer Dr Andreas Fouras said the pilot program would "help open the door to the huge US diagnostics market and take us closer to realizing the commercial potential of our innovative technology".

Dr Fouras said that the company recently unveiled an operational XV Scanner at Sydney's Prince of Wales Hospital (BD: Mar 17, 2022).

"While the US pilot [program] has been slower to get moving than we anticipated, we are excited by the momentum it injects into our commercialization efforts at this time," Dr Fouras said.

4D was unchanged at 76 cents.

AMPLIA THERAPEUTICS

Amplia says that following ethics approval, it will begin a 38-patient, open-label, single-arm phase II trial of its AMP945 in patients with advanced pancreatic cancer.

In February, Amplia said the Garvan Institute had shown that oral AMP945 improves the effectiveness of gemcitabine (Abraxane) by 33 percent for pancreatic cancer, in mice (BD: Feb 17, 2022).

Today, Amplia said the phase II trial's primary endpoint would be patients' objective response.

The company said the trial would have two parts, with the first part designed to identify the optimal dose of AMP945 in about 12 patients.

Amplia said that in this part, first-line patients with advanced pancreatic cancer would be treated with a range of doses of AMP945, in addition to clinically established doses of a current standard-of-care combination therapy consisting of gemcitabine and nab-paclitaxel.

The company said that following selection of the optimal dose, about 26 first-line patients would be treated with the optimized dose of AMP945 in combination with gemcitabine and nab-paclitaxel.

Amplia said the ethics approval allowed the trial to begin in New South Wales, and a second approval allowing a trial in Victoria was expected "in the very near future".

Amplia managing-director Dr John Lambert said the ethics approval was "very exciting".

"Given the challenges that have historically been faced in the clinic by new treatments for this devastating disease, we believe that the best opportunity to improve treatment outcomes is to enhance the efficacy of current standards of care," Dr Lambert said.

"The pre-clinical data that we have generated to date has consistently indicated that AMP945 may be able to significantly improve the effectiveness of standard gemcitabine [and] nab-paclitaxel combination therapy," Dr Lambert said.

The company said that an interim analysis of trial data was expected in mid-2023.

Amplia was up half a cent or 3.6 percent to 14.5 cents.

RACE ONCOLOGY

Race says it is awaiting a further approval to begin a 60-patient phase I trial of Zantrene for acute myeloid leukaemia (AML) and myelodysplastic syndrome (MDS).
In March, Race said Zantrene, or bisantrene, with decitabine was 'highly effective' against extra-medullary acute myeloid leukaemia, in mice (BD: Mar 17, 2022).
Today, Race said it has ethics approval and was seeking a site-specific 'research governance office' approval from the Calvary Mater Newcastle Hospital in New South Wales, which it expected in four to eight weeks.
The company said the phase I, open label trial would lead to a phase II dose expansion phase.
Race said the first part of the trial would use Zantrene as a high dose, single agent treatment over seven days in up to 30 patients with extra-medullary acute myeloid leukaemia who are able to tolerate high intensity chemotherapy, followed by one or more cycles of consolidation treatment of Zantrene in combination with Ara-C, or cytarabine, a standard-of care-drug.
Race said the second part would use Zantrene as a low dose fat mass and obesity (FTO)-gene targeting agent in combination with oral decitabine and cedazuridine for up to 10 myelodysplastic syndrome or acute myeloid leukaemia patients unwilling or unable to undergo high intensity chemotherapy in the dose escalation phase and a further 20 patients in the expansion stage.
The company said the first part of the trial's primary endpoint would be complete response or a complete response with incomplete haematological recovery.
Race said the second part patients' primary endpoint was safety and tolerability.
The company said that key secondary endpoints were overall response and the number of patients able to have a transplant and time to transplant, pharmaco-kinetics, biomarker status, event-free survival and overall survival.
Race said the trial was expected to take at least three years to complete with full patient recruitment over 18 months.
Race fell two cents or 0.7 percent to $2.75.

CANN GROUP

Cann Group says Glaxosmithkline Consumer Healthcare will pay GBP100,000 ($A173,000) to evaluate distribution and marketing of its Satipharm cannabidiol capsules.
Cann Group said that Glaxosmithkline would have 60 days' exclusivity from the delivery of its final phase III Satipharm trial report to evaluate the commercial potential of the over-the-counter low-dose cannabidiol (CBD) product.
The company said the agreement gave Glaxosmithkline the right of first negotiation for the marketing, sale and distribution of Satipharm in Australia, with negotiations to run in parallel with the evaluation period.
Cann Group said the agreement granted Glaxosmithkline first rights to negotiate commercialization rights for markets outside of Australia.
Cann chief executive officer Peter Crock said the company's ability "to produce a [cannabidiol] capsule that presents as a regular pharmaceutical and has proven benefits in terms of stability and bioavailability has attracted interest from a number of potential distribution partners".
Cann was up half a cent or 1.8 percent to 28.5 cents with 2.1 million shares traded.

CORRECTION: AROVELLA THERAPEUTICS

Yesterday's report incorrectly said that the US Patent and Trademark Office approved Arovella's patent for its invariant natural killer T-cell platform for treating blood cancers.
In fact, the patent relates to the use of anagrelide for the treatment of metastatic disease and not the invariant natural killer T-cell platform for treating blood cancers.
The company said it was "focused on developing its invariant natural killer T-cell platform to treat blood cancers", which the Tuesday sub-editor incorrectly assumed was anagrelide.
Arovella said that anagrelide was being developed for "metastatic disease in patients who have certain solid tumor cancers".
The Tuesday sub-editor has been given leave to research cancers and their treatments and, pending results, might be granted remission.
Arovella was unchanged at 4.1 cents.

NANOSONICS

Australian Super says it has become substantial in Nanosonics with 15,091,912 shares, or 5.00 percent of the company.
The Melbourne-based Australian Super said that between November 1, 2021 and March 30, 2022, it bought and sold shares in Nanosonics at prices ranging from $3.72 to $6.44 a share.
Nanosonics fell one cent or 0.25 percent to $3.96 with 550,618 shares traded.

MICROBA LIFESCIENCES

Perennial Value Management says it has become substantial in Microba with 40,651,376 shares, or 14.82 percent.
The Sydney-based Perennial said that on April 5, 2022, it bought 40,651,376 shares for $18,293,119, or 45 cents a share.
Yesterday, MIcroba listed on the ASX, having raised $30 million at 45 cents a share to commercialize its gut microbiome tests and treatments (BD: Apr 5, 2022).
Microba was up 2.5 cents or 7.1 percent to 37.5 cents with 2.6 million shares traded.

MICROBA LIFESCIENCES

Microba says it has appointed Prof Trent Munro as its head of therapeutics, effective from today.
Microba said Prof Munro had most recently been the National Biologics Facility director, Rapid Response Vaccine pipeline program director, Centre for Biopharmaceutical Innovation director and a senior group leader at the University of Queensland's Australian Institute for Bioengineering and Nanotechnology.
The company said that Prof Munro had previously been an Amgen executive director.
Prof Munro's University of Queensland research profile said he held a Doctor of Philosophy from the University of Queensland, and a Bachelor of Science from James Cook University.

MEDADVISOR

Medadvisor says that managing-director Robert Read intends to retire as its chief executive officer, but continue as a director for the time being.

Medadvisor said the company would appoint a US-based chief executive officer but Mr Read was “unable to relocate due to family reasons”.

The company said that having acquired and integrated Adheris, about 80 percent of revenues and earnings were sourced in the US and a search had begun for a suitable group chief executive officer based in that country.

Mr Read told Biotech Daily that he would “support the company as needed through the transition and beyond” and continue as a non-executive director.

Medadvisor was up one cent or 3.9 percent to 26.5 cents.